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IN THE CIRCUIT COURT OF OHIO COUNTY, WEST VIRGINIA
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 3
 4
 5
      IN RE: TOBACCO LITIGATION
 6
                                      CIVIL ACTION
 7
                                         NO. 00-C-6000
   (MEDICAL MONITORING CASES) (Judge Arthur M. Recht)
 8
9
                                 Judge Tod J. Kaufman)
10
11
12
13
14
            Deposition of:
15
16
            WILLIAM SCHAFFNER, MD
17
18
             Taken on behalf of the Plaintiffs
19
20
            August 28, 2000
21
22
23
2.4
25
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       2.
      APPEARANCES:
 1
 2
      For Plaintiffs:
                         Frederick J. Jekel
                         Attorney at Law
 3
                         Ness, Motley, Loadholt,
                          Richardson & Poole
 4
                         28 Bridgeside Boulevard
                         P. O. Box 1792
                         Charleston, SC 29465
 5
                         843/216-9188
 6
                                 and
      For Plaintiffs: Cindy Stine
 7
      (By telephone)
                        Attorney at Law
                         Golberg, Jennings & White
 8
                         1030 5th Avenue
                         Pittsburgh, PA
 9
     For Defendant Stephen McConnell
Philip Morris: Attorney at Law
10
      (By telephone)
                        4000 Bell Atlantic Tower
11
                         1717 Arch Street
                         Philadelphia, PA 19103
12
                         215/994-2281
13 For Defendant: Travis Fliehman
                         Attorney at Law
14
                         Jackson & Kelly
                         P. O. Box 553
                         Charleston, WV 25322
15
                         304/340-1242
16
      For Defendant:
                         Robert Hogan
17
                         Attorney at Law
                         914 5th Avenue
18
                         P. O. Box 6457
```

19	Huntington, WV 25701 304/522-9100
20	For Defendant James Cox
21	Lorillard: Attorney at Law (By telephone) Thompson Coburn
22	One First Star Plaza St. Louis, MO 63101
23	314/552-6024
24 25	
23	A. WILLIAM ROBERTS, JR. & ASSOCIATES
1	For the Defendant John W. O'Tuel, III
2	R. J. Reynolds: Attorney at Law Womble, Carlyle, Sandridge
3	& Rice Suite 2100
4	150 Fayetteville Street Mall P. O. Box 831
5	Raleigh, NC 27602 919/755-8133
6	and William E. Latham, II
7	Attorney at Law Womble, Carlyle, Sandridge
8	& Rice 200 West Second Street
9	P. O. Drawer 84 Winston-Salem, NC 27102
10	336/721-3765
11	
12	
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18	
19 20 21 22 23 24 25	A. WILLIAM ROBERTS, JR. & ASSOCIATES
1 2	STIPULATION
3	The deposition of WILLIAM SCHAFFNER,

MD, was taken by counsel for the Plaintiffs at the 4 5 Vanderbilt Medical Center North, B-1124, Nashville, Tennessee, beginning at 1:00 p.m. on 6 7 August 28, 2000, for all purposes under the West Virginia Rules of Civil Procedure. 8 9 The formalities as to notice, 10 caption, and reading and signing of the deposition 11 are waived. All objections, except as to the form 12 of the questions, are reserved to the hearing. 13 It is agreed that Nancy Satoloe, 14 being a Notary Public and Court Reporter for the 15 State of Tennessee, may swear the witness, and 16 that the reading and signing of the completed 17 deposition by the witness are not waived. 18 19 20 21 22 23 24 25 A. WILLIAM ROBERTS, JR. & ASSOCIATES 5 1 WILLIAM SCHAFFNER, MD 2 was called as a witness, and after having been first duly sworn, testified as follows: 3 4 5 EXAMINATION 6 BY MR. JEKEL: 7 Good afternoon, Dr. Schaffner. My Q. 8 name is -- is it Schaffner? 9 Α. Yes. You'll have to speak up so that the 10 folks on the other end of the line can hear us. 11 12 I'm sure they'll let us know if they don't hear 13 you. 14 My name is Fritz Jekel. I'm one of 15 the attorneys representing the plaintiffs in this 16 action. Have you had your deposition taken 17 before? 18 Α. I have. 19 All right. You know the ground Q. rules. It will be important for you to allow me 20 21 to finish my question before you give an answer. 22 Also allow the folks participating on the 23 telephone an opportunity to let us know if they 24 can't hear and for counsel to raise an objection. 25 If you answer a question, I will A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 assume you understood it. If at any time you need 2 more information in which to answer my question, 3 let me know and I'll do my best to make it 4 answerable. 5 If you need a break at any time, let 6 me know and we'll go from there. 7 Dr. Schaffner, do you have a file in 8 this matter? 9 Α. Yes. 10 Q. Did you bring it with you? 11 I did. Α. 12 Can I take a look at it? Q.

13 For the benefit of the folks 14 participating by phone, I'm just going to identify 15 the materials that are in the doctor's file. 16 The first item is his Expert Witness Disclosure. The second item is the Third Amended 17 18 Complaint in the Blankenship matter. The next item is the Revised Report of David Burns; it has 19 20 some highlighting and some tabs. The third --21 would you identify -- or fourth item, sorry, would 22 you identify this for the record? 23 This is a report of Dr. Donald B. 24 Luria. 25 Okay. All right. The next item is A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 from the May, 1998 Scientific News Front article. Is that the name of the publication? 2 3 The West Virginia Medical Journal, I'm sorry, May 1988, Volume 84, page 177, "The 4 5 Declining Incidence and Changing Epidemiological Pattern of Tuberculosis." 6 7 The next item in the report is a --8 can you give us the source for that, Dr. 9 Schaffner? 10 These are a series of tables which we 11 got from the CDC, Centers for Disease Control and 12 Prevention website. The tables are entitled "Tuberculosis Cases" and "Case Rates Per 100,000 13 Population by State, " and then I have them for the 14 15 years 1996 through 1999. 16 All right. The next item is an Q. 17 article from the Lancet, Volume 354, July 10th, 18 1999 entitled "Early Lung Cancer Action Project: Overall Design and Findings from Baseline 19 20 Screening." 21 The next item is an editorial from 22 the Journal of the National Cancer Institute, Volume 92, No. 16, August 16th, 2000 entitled 23 "Overdiagnosis: An Underrecognized Cause of 24 25 Confusion and Harm in Cancer Screening." A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 The next item is also from the 2 Journal of the National Cancer Institute, Volume 3 92, No. 16, August 16th, 2000 entitled "Lung 4 Cancer Mortality in the Mayo Lung Project: Impact 5 and Extended Followup." 6 The next item is also, I guess, from 7 the Journal of the National Cancer Institute. 8 looks to be an article entitled "Lung Project 9 Update Raises Issue of Overdiagnosing Patients" by 10 a Laura Newman. 11 Excuse me. 12 The next article -- is this from the 13 CDC? 14 This is an article from the journal 15 Clinical Infectious Diseases. Okay. It's entitled "Histoplasmosis 16 17 and Blastomycosis." Did I pronounce that 18 properly? By a Bradsure. 19 This next article is from the 20 Seminars in Respiratory Infections, Volume 5, No. 21 2, June, 1990 entitled "Histoplasmosis: Update

```
22
       1989."
23
                    Is BMJ the British Medical Journal?
24
              Α.
                    Yes.
25
                   The next article is from the British
              Q.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
       Medical Journal, Volume 321, August 5th, 2000
 1
       entitled "Smoking, Smoking Cessation, and Lung
       Cancer in the UK since 1950: Combination of
 3
 4
       National Statistics with Two Case Control Studies"
 5
       by Peto, P-e-t-o, et al.
                    The next article is from the American
 6
 7
       Review of Respiratory Disease, Volume 105 from
 8
       1972 entitled "A Combined Field and Laboratory
 9
       Epidemic of Histoplasmosis Isolation from Bat
10
       Feces in West Virginia."
11
                   Do you know what journal this is
12
       from, Doctor?
13
                   I can't say for sure.
14
                  Okay. It's an article entitled
15
       "Early Lung Cancer Action Project: Overall Design
       of Baseline Screening" by Henschke,
16
17
       H-e-n-s-c-h-k-e, Claudia I., it's dated -- I don't
18
       know if it has a date in here.
19
                   The next item is from the First
20
       International Conference on Screening for Lung
21
       Cancer, October 1st through 3rd, 1989. It sends a
22
       statement.
                    The next item is from Chest, June,
2.3
24
       2000 article entitled "Correlation of Tumor Size
25
       and Survival in Patients with Stage 1A Non-Small
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       10
       Cell Lung Cancer" by Patts, et al.
                    The next document is, I guess, from
 2.
 3
       the National Cancer Institute, is that what this
       is called, the PDQ, Supportive Care? This is just
 4
 5
       a statement from the NCI on screening for lung
       cancer?
 6
 7
                   Looks that way to me.
 8
                  All right. Printed off the Internet,
              Ο.
 9
       4-27-2000.
                   The next document is by -- this is a
10
       bit tedious, Doctor, but it will save us some
11
12
       time. It's an article by Dr. Strauss,
13
       S-t-r-a-u-s-s, "Lung Cancer Screening in
14
       Randomized Population Trials."
15
                    The next article is by Miettinen,
16
       M-i-e-t-t-i-n-e-n, "Screening for Lung Cancer: Do
17
       We Need Randomized Trials?"
18
                    The next article is by Diederich,
19
       D-i-e-d-e-r-i-c-h, and Lenzen, L-e-n-z-e-n,
20
       entitled "Radiation Exposure Associated with
21
       Imaging of the Chest: Comparison of Different
22
       Radiographic and CT Techniques."
23
                   We also have the expert report of
24
       Alfred B. Watson. We have a copy, the next item
25
       is a copy of the proceedings on the Second
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       National Conference on Histoplasmosis from 1971;
 2
       is that correct?
              Α.
                  Yes.
```

```
Appears to be a book by Charles C.
              Q.
       Thomas, Publisher?
 5
             A. And it's Chapter 15 in that book by
 6
 7
       Ajello, A-j-e-l-l-o, "Distribution of
 8
       Histoplasmacapsulatum in the United States."
 9
                    Thank you, sir.
10
                    The next article appears from the
11
       European Respiratory Journal, 1996, entitled
12
       "Clinical Spectrum of Pulmonary and Pleural
13
       Tuberculosis, a Report of 5,480 Cases" by Aktogu,
14
       A-k-t-o-g-u, et al.
15
                    The next article is from the Journal
16
       of Thoracic Imaging, Volume 7, Issue 4, 1992
17
       entitled "Clinical Manifestations of Pulmonary
18
       Fungal Infections."
19
                    Chapter 36, do you know, is that the
20
       only chapter?
21
              Α.
                    Yes.
22
                    The next document is Volume 1,
              Ο.
23
       Textbook of Respiratory Medicine, Second Edition
       by Dr. Muray and Nadell, that's M-u-r-a-y, Chapter
24
       36, "Fungal Infections" by Drs. Davies and Sarosi,
25
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       12
 1
       S-a-r-o-s-i.
 2
                    The next article is from, I guess,
 3
       it's Surgery Today entitled "Pulmonary
       Histoplasmosis in Japanese Male: Report of a
 4
 5
       Case." It's from 1998.
 6
                    We have another chapter from the
 7
       Textbook of Respiratory Medicine, Second Edition.
 8
       This happens to be Chapter 35, "Tuberculosis and
 9
       Other Mycobacterial Diseases" by Hopewell and
10
11
                    The next document, Acta Radiological,
12
       a Denmark publication entitled "Imaging of
13
       Tuberculosis-Experience from 503 Patients" by a
14
       Nyman, N-y-m-a-n, et al., 1996.
15
                    The next article -- I don't know
16
       where it's from, but it's entitled "Pulmonary
17
       Infections Mimicking Cancer: A Retrospective,
18
       Three-year Review" by Dr. Rolston, R-o-l-s-t-o-n,
19
       et al.
                    If, you know, if we had a list of
20
21
       these publications, it might move things along.
22
                    But the next one is from the Journal
23
       of Thoracic Imaging, 1992 entitled "Thoracic
24
       Histoplasmosis" by Drs. Rubin, et al.
25
                    The next article is from -- let's see
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       where it's from. The International Journal of
 2
       Tuberculosis and Lung Disease, 1998, "Pulmonary
 3
       Tuberculosis in the Adult in Low Prevalence Area:
 4
       Is the Radiologic Presentation Changing" by Dr.
 5
       Brande, B-r-a-n-d-e. I think it's actually Van
 6
       den Brande. V-a-n space small d-e-n.
 7
                    The next item is Textbook of
 8
       Pulmonary Diseases, Fifth Edition, Volume 1,
 9
       edited by Dr. Baum, B-a-u-m, and Wallinski,
10
       Chapter 21 on Tuberculosis by Wallinski, 1994.
11
                    The next article is entitled "Update:
12
       The Radiographic Features of Pulmonary
```

13 Tuberculosis, " March, 1996 in the AJR by Woodring, 14 W-o-o-d-r-i-n-g. 15 And the last in the stack, Diagnosis 16 of Diseases of the Chest, Fourth Edition, Volume 2 17 by Fraser, F-r-a-s-e-r, Chapter 27 on 18 Mycobacteria. Do you know if that's the only 19 chapter in there? 20 Α. I think that's the only chapter. All right. Does this comprise your 21 22 entire file in this matter? 23 Α. Yes. 24 Is this the entirety of the materials 25 you will be relying on for your expected testimony A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 in this action? 2. A. Well, in addition to this, I'll be 3 relying on my background and experience and my general knowledge of the medical literature. 5 Q. Any other textbooks or articles that 6 spring to mind that you would expect to testify at 7 trial about? Not at the moment. 8 Α. 9 Okay. Did you compile these 10 materials yourself, Dr. Schaffner? 11 A. The materials in there that came from 12 me are the tuberculosis tables. 13 Okay. Q. And the chapter by Dr. Ajello on 14 Α. 15 Histoplasmosis. 16 Q. All right. Why don't we take those 17 out. There's the tuberculosis statements. 18 The other materials that are in this 19 considerable stack, they were provided to you from 20 where? 21 Mr. O'Tuel provided those. 22 So the lawyers for RJR provided you Q. 23 the rest of your reliance materials; is that 24 correct? 25 MR. LATHAM: Object to the form of A. WILLIAM ROBERTS, JR. & ASSOCIATES 15 1 the question. 2 THE WITNESS: No. They just provided 3 the rest of the materials in this list. 4 BY MR. JEKEL: 5 Did you compile a list and provide it Q. 6 to counsel for RJR and say, can you obtain copies 7 of these articles for me to rely upon, or did the 8 counsel for RJR come to you and say, Dr. 9 Schaffner, here is a list of materials we would 10 like for you to rely on for your testimony, or 11 something else? 12 Α. Well, it was nothing quite like that. 13 I know we had conversations, and I said, I'm going 14 to provide some materials. If you think you have something -- my comments to them -- that you think 15 16 I might -- that are in your files that would save 17 me time, and I think this was the product of that. 18 Q. All right. Have you read all of the 19 articles in this stack? 20 Not from first word to last, but I've 21 looked at them all.

```
22
                  Okay. Are there some in here that
             Q.
23
       you've looked at that you do not anticipate
24
       relying on and that we cannot discuss today?
25
             A. Well, I'm not entirely sure what you
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       mean by that.
              Q. Well, are there any materials in here
       for which you do not anticipate relying for the
 3
 4
       basis of your expected opinions at trial? After
 5
       you reviewed it all, did you say, you know, I
 6
       don't need this? Anything like that?
 7
                  Well, I didn't say that, so I haven't
       thought about it in that kind of a selective way.
 8
 9
             Q. All right. Well, thinking about it
10
       now, are there any articles or texts or anything
11
       in this stack that we just went through that as
12
       you sit here today you think to yourself, I'm not
13
       going to need this for my trial testimony, I will
14
       not rely on it?
15
                  Well, actually, my reliance comes
             Α.
16
       from a vastly larger base than this because it's
17
       my whole experience and my general knowledge of
18
       the literature. I haven't thought of this as a
19
       special collection of materials that I will only
20
       go to, so I haven't given it that kind of thought.
21
                  Do you know why counsel for RJR
22
       provided you some of these articles? Did they
23
       tell you what the purpose in that was?
24
             A. Oh, I mean, clearly, I'm an
25
       infectious diseases person, and that's where I
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       17
       expect most of my comments to be, and we had had
       some discussions about my thoughts in that area,
 3
       and I think they responded to that. For example,
       these textbook chapters on Histoplasmosis and
       Tuberculosis, I talked about those illnesses, and
 5
       I think they were just trying to be helpful. I
 6
 7
       mean, there are lots of other textbooks and other
 8
       parts of the medical literature that relate to
 9
       histoplasmosis and tuberculosis that are available
       and that I have seen and used in the past.
10
11
             Q. The textbook of Respiratory Medicine,
12
       is this a textbook that you use here at the
13
       college?
14
                    I'm not entirely sure what you mean
15
       by that. It may well be in the library and may be
       in the personal libraries of many people here. I
16
17
       don't know that for a fact.
18
                  As I understand it, you do teach some
             Q.
19
       medical students here?
20
             Α.
                 Oh, yes.
21
                   Do you teach them in respiratory
22
       medicine?
23
                    Is that "you" large or "you"
             Α.
24
       personally?
25
                   You personally.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
                    Of course, but I'm not a
              Α.
 2
       pulmonologist, and that's a text that's written by
       pulmonologists, but for sure infectious diseases
```

involve the respiratory tract, and we teach that. 4 5 Q. Is this a textbook that you use in 6 any of the courses that you, Dr. Schaffner, teach 7 here at the medical college? We don't assign texts to courses in 8 9 the way that it's done in undergraduate school. The medical library is available to the medical 10 students. I have gone into that text from time to 11 time in the past. I'm familiar with the text 12 13 generally. I know that it exists. 14 Q. Fine. Have you ever referred to this 15 chapter in your teachings here at the college, the 16 section on Fungal Infections? I can't recall that I have. 17 Do you know what in here, in this 18 Q. 19 chapter you will rely upon for your opinions in 20 this matter? Well, it's a difficult question for 21 Α. 22 me to answer. I don't know that there's anything 23 that I could point out, a sentence or paragraph, 24 et cetera, or section that relates specifically to 25 my anticipated testimony, although --A. WILLIAM ROBERTS, JR. & ASSOCIATES 19 1 Okay. I'm sorry. 2 Although I'm trying to be responsive to your comments. This is a general chapter on 3 Fungal Infections by Scott Davies and George 4 Sarosi. The area that I have talked with the 5 6 attorneys about and is reflected in other articles 7 in this stack is histoplasmosis, so I dare say 8 that would be the area that would receive most of 9 my attention. 10 So if there's anything in that Q. chapter on histoplasmosis, that's what you might 11 12 use this for. Other than that, -- when was the 13 last time you looked at this chapter? 14 A. It was either Saturday night or last 15 night. Q. Did you review the whole thing? A. I looked through it. I looked 16 17 through all of this material. 18 19 Q. Do you know if this chapter mentions 20 the word lung cancer? 21 A. No. I don't know that. 22 Dr. Schaffner, when were you first 23 retained to provide expert services in the 24 Blankenship matter? 25 A. Fairly recently, sometime in the last A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 several months. I couldn't tell you more 2 specifically than that. 3 Q. Was it beginning of the summer, let's 4 say, April? Or the end of April? Was it after 5 tax day, do you know? 6 I don't know. Α. 7 Is there anything in your file or your desk book or your calendar that might reflect 8 9 the exact date upon which you were retained to 10 provide services in this matter? 11 A. 12 Have you rendered a bill to whoever Q.

13 has retained you for your services in this matter 14 to date? 15 Α. No. 16 Do you anticipate issuing a bill for Q. 17 your services to date? 18 A. I anticipate submitting a bill for 19 services rendered. It may not be just this date; 20 this may continue. 21 Q. Yes. I assume that would include 22 time preparing your expert disclosure? 23 A. Yes. 24 Your time talking with the attorneys Ο. 25 about your areas of expertise? A. WILLIAM ROBERTS, JR. & ASSOCIATES 21 1 Α. Correct. 2 Your time reviewing the stack of Q. materials and other reliance materials? 3 4 Correct. 5 Q. Okay. Who retained you in this 6 matter? 7 Who is your client? 8 Mr. O'Tuel's firm. Α. 9 I'd like to discuss the manner in 10 which you were retained. Was it a telephone 11 conversation? 12 MR. LATHAM: Object to the form of 13 the question. What do you mean by manner in which 14 you were retained? 15 BY MR. JEKEL: 16 Let's talk about the first contact Ο. 17 from the counsel for RJR. I'm assuming they made contact with you, Dr. Schaffner, and said, Dr. 18 19 Schaffner, we're counsel for RJR. We'd like to 20 retain your services or we'd like to discuss with you the possibilities of retaining your services. 21 22 Did anything like that ever take place? 23 I'm sure something like that took 2.4 place. 25 Do you remember the first contact you A. WILLIAM ROBERTS, JR. & ASSOCIATES had with Mr. O'Tuel or anyone from Mr. O'Tuel's 1 2 firm? 3 Α. Not with specificity. 4 Do you know if it was a meeting in Q. 5 person or on the telephone or something else? 6 Over the computer? 7 Α. It was not over the computer. 8 Q. Okay. Do you recall him coming to 9 you in person? 10 It may have been while we were Α. 11 together or it may have been on the phone. 12 Q. When were you together? 13 Α. I'm sorry? 14 Let me back up. Q. 15 Prior to your involvement in the 16 Blankenship matter, had you been retained by Mr. 17 O'Tuel's firm in the past to provide expert 18 services/testimony in tobacco-related litigation? 19 Α. Yes. 20 How long ago was that? Q. 21 Or when was the first time you

```
22
       provided services to Mr. O'Tuel's firm in
23
       tobacco-related litigation?
24
                 I won't be able to tell you that
25
       specifically, but order of magnitude to the best
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
       of my memory at this moment, let's say a couple of
1
 3
                   Okay. Fair enough.
 4
                   Have you issued bills to Mr. O'Tuel's
 5
       firm for any of the work you've done in any
 6
       tobacco-related litigation?
 7
             Α.
                   Yes.
8
                  Do you maintain those files on your
9
       computer?
10
             A. No.
11
                  Do you maintain hard copies of those
             Q.
12
       invoices?
13
                  I think once they're paid, I discard
14
      most of them. I have very -- not very regular
15
       files for my night job.
             Q. The fees that you generate and make
16
17
       from the tobacco-related litigation, do those go
18
       to a personal business that you have, or do they
19
       go to the University? What happens with those
20
       fees?
21
                   The University permits us to do this
       sort of consultation, and we are permitted to
22
23
       retain the fees that we charge.
24
             Q. Since you have been consulting with
25
       Mr. O'Tuel's firm, do you know if Mr. O'Tuel's
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       24
       firm has always been representing RJR?
                  I don't know the answer to that.
 2.
 3
                  Did you know as it relates to your
 4
       work in the Blankenship case that Mr. O'Tuel's
       firm was representing RJR?
 5
             A. I knew that they were representing a
 6
7
       firm in the tobacco industry, but -- they may have
8
       told me, but I did not take notice of the specific
9
       firm.
                   Do you delineate on your income tax
10
11
       return the fees that you generate from your
       tobacco litigation expertise or the work you do in
12
13
       the tobacco litigation?
14
             A. Delineate from or how?
15
                  Do you include it on your personal
             Ο.
16
       income taxes?
17
             A. Well, I include on my personal income
18
       taxes all my income, you bet.
19
             Q. All right. Does Mr. O'Tuel's firm
20
       send you some kind of form so you can report
21
       accurately the amount of money you've made?
22
             A.
                  I can't answer that specifically, but
23
       that might well be.
24
                  Can you give me an estimate of the
25
       total amount of fees you've generated as a result
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       25
1
       of your work in the tobacco litigation?
 2
             A. Not as I sit here.
                   How much do you charge an hour,
              Q.
```

```
4
       Doctor?
             A.
 5
                    $550.
 6
                   Is that for generation of the expert
 7
                   It's for everything.
 8
9
                    Everything. Review of these
              Q.
10
       materials?
11
                    That's what the word means,
              Α.
12
       everything.
13
                    I just want to make sure.
14
                    Can you give me an estimate of how
       many hours you've put into this case here today?
15
16
                   It would be an estimate.
              Α.
17
                   That's fine.
              Q.
                   Let's say 10, 11.
18
              Α.
19
                   Would it be fair to say, Dr.
              Q.
20
       Schaffner, that over the last two years in the
21
       tobacco-related litigation that you have made over
22
       $100,000 in expert witness fees?
23
              Α.
                   Heck no.
24
                   No? Would it be more than $50,000?
              Q.
25
              Α.
                   No.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       26
 1
                    Do you have a figure in mind?
 2
                   No. But it's a lot less than
              Α.
       $50,000. A lot less.
 3
 4
                  All right. How do you keep your
              Q.
 5
       hours for your work in this matter?
              A. I just jot them down.
 6
 7
              Q. And who generates the invoice?
 8
                  My secretary/administrative
              Α.
 9
       assistant.
                  And how have you demarked the
10
             Q.
       Blankenship file, if you will?
11
12
                    Do you have a file name or number?
13
                    What do you mean by demarked?
              Α.
14
                    Well, just how you keep track of it,
              Ο.
15
       like when you are writing down your hours as they
16
       relate to the Blankenship work, do you write down
17
       Blankenship, or have you assigned a file number,
18
       whatever that file number or name may be for your
19
       work in this matter?
             A. I believe it's -- I may have just
20
21
       called it Medical Monitoring.
22
              Q. Okay. That's fair enough.
23
                   I don't know whether it's fair, but
              Α.
24
       it's accurate, or to the best of my ability.
25
                  Do you know in how many other cases
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       you have provided expert services to Mr. O'Tuel's
       firm?
 2
 3
                    I believe two.
 4
             Q.
                   Do you recall the names of those
 5
       actions?
                  Well, I remember that the plaintiff
 6
 7
       for both had the same name, and the name is Neri,
 8
       N-e-r-i, and that was also an infectious
 9
       disease-related issue.
10
                   Other than Mr. O'Tuel's firm, have
11
       you been retained by other law firms to provide
12
       expert services in tobacco-related litigation?
```

13 I have not. 14 Did you give testimony, deposition Q. 15 and/or trial testimony in the Neri case? 16 A. I think not. 17 Okay. Do you know if you issued an 18 expert witness disclosure in that action? A. I couldn't tell you as I sit here. Q. If you did, would you have those 19 20 files on your computer in your office? 21 22 A. You credit me with more computer 23 expertise than I have. I don't know whether they 24 have been retained there in the office or not, and 25 I don't even know if they are there. A. WILLIAM ROBERTS, JR. & ASSOCIATES Okay. How about the expert witness 1 Q. 2 disclosure in this action? Did you or someone on 3 your staff type this up for you? A. I don't think so. Did you write it out, send it to 5 6 someone, ask them to type it up for you and review 7 it? 8 Well, variants of that are often the 9 case when I do this. I think, I think this one 10 resulted from a discussion between me and Mr. 11 O'Tuel. 12 Okay. Would that have been in 13 person, on the phone, over the computer, or do you 14 not recall? 15 Α. I best say I don't recall. I think 16 it was on the phone, but I wouldn't want to be 17 held to that. 18 Q. Okay. If --19 Α. That may not be right. I can't tell 20 you. 21 Would you have made an entry on a slip of paper, half-hour discussion with Mr. 22 23 O'Tuel, witness disclosure form or something 24 similar to that? 25 A. It would have been less -- it could A. WILLIAM ROBERTS, JR. & ASSOCIATES have been that specific or it might just have been 1 2 consultation with Mr. O'Tuel. 3 Q. Do you know if you've ever made an 4 entry for purposes of billing Mr. O'Tuel's firm 5 for drafting your expert witness disclosure form? 6 A. Excuse me. Tell me the question 7 again. Have I --8 Q. Ever made an entry for purposes of 9 billing Mr. O'Tuel's firm for your services in 10 this action for drafting an expert witness 11 disclosure? 12 A. I don't know if it's noted that 13 specifically, but I suspect I have made an entry. 14 Q. Do you know how much time you put in 15 drafting this expert witness disclosure? A. I don't recall that at the moment. I 16 17 mean, we had substantial discussion before that, 18 and it may not have been even on that exact 19 moment, you know, I have had several contacts with 20 Mr. O'Tuel and Miss Crooks about this. 21 Q. I'm sorry. The other person you

```
22
       mentioned was a Miss --
23
             A. Susan Crooks.
24
                    Is she also an attorney with Mr.
25
       O'Tuel?
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       30
 1
                    Indeed.
                   Since you've been retained in this
              Ο.
 3
       matter, can you identify for me at least the
 4
       number of phone conversations or face-to-face
 5
       meetings you have had with representatives from
       Mr. O'Tuel's firm discussing your testimony in the
 6
 7
       Blankenship case?
 8
                  Not off the top of my head, but I
              Α.
 9
       could get that for you.
10
                  And where would you get that
             Q.
11
       information?
12
                 From my office, I think, or it's
             Α.
13
       either there or at home.
14
              Q.
                  Okay. We won't make you do that
15
       right now. It may be something we request later
16
17
                    The information though from where you
18
       would get that though, would that be in your
19
       billing notes or the entries that you make and how
20
       much time you spend on the case?
21
              Α.
                    Yes.
22
                    Isn't it true that Mr. O'Tuel or
              Q.
23
       someone at Mr. O'Tuel's firm drafted this Expert
24
       Witness Disclosure and sent it to you and asked
25
       you if you would approve it?
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       31
                    That was the culmination of the
 1
 2.
       process, yes.
 3
              Q. Did you see any drafts of this
 4
       document that you marked up, had questions about
 5
       or revisions to?
 6
                   They blur together. I can't remember
              Α.
 7
       specifically.
 8
                   Can you in looking at the expert
 9
       report, can you tell me certain areas in which you
       may have made changes to or sentences that you
10
11
       said, we need to change this?
12
              Α.
                  I could not be that specific today.
13
                   Okay. Is it your recollection that
14
       there were, in fact, prior drafts to this report
15
       for which you made changes?
16
                   Is that my recollection, is that your
17
       question?
18
              Q.
                    Yes.
19
                    That's not my recollection. My
              Α.
20
       recollection is not sufficiently specific as to
21
       the generation of this specific document.
22
                   So it may have been that this was the
23
       first draft, you looked at it, said it's fine,
24
       I'll go with it?
25
                  That's possible.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       32
 1
                    But this was not generated off of
 2
       your computer, was it?
                   No. It was not.
```

This came from counsel for RJR, did 5 it not? 6 Α. Yes. 7 And the footer on the bottom there, 8 the Raleigh footer, do you know what any of that 9 10 I suspect -- this is sworn testimony, 11 and we're hard up against my knowledge of 12 computers, but I think that that will let someone 13 whose computer it is get to that document. 14 Q. But that's not on your computer? 15 No. It's not. Α. 16 And you really don't know what that Q. 17 number means except that it's something that Mr. 18 O'Tuel's firm put on the bottom of your expert 19 report, isn't it? 20 I dare say. Α. 21 MR. JEKEL: I want to mark this as an 22 exhibit, but I don't know if you want me to mark his copy from his file or if we want to make 23 24 copies of it after the deposition is done. Do you 25 gentlemen have a preference? Does Dr. Schaffner A. WILLIAM ROBERTS, JR. & ASSOCIATES 33 1 have a preference? 2 MR. LATHAM: Up to you. THE WITNESS: Doesn't make any 3 difference. I'd like to just retain a copy of 4 5 that. It doesn't have to be those two pieces of 6 paper. 7 MR. JEKEL: Let's go ahead and mark 8 Dr. Schaffner's report as Schaffner Exhibit 1. 9 (Whereupon, the above-mentioned 10 report document was marked Exhibit No. 1.) BY MR. JEKEL: 11 12 Before we go over your report, Dr. Q. Schaffner, I'd like to ask you if at any time 13 consulting with Mr. O'Tuel's firm, did you ever 14 15 ask them why they came to you or how they got your 16 name or why they sought you out as an expert in 17 this area? 18 My memory of that is that they were 19 working with a colleague, and he referred them to 20 me. 21 Q. Do you know who that colleague would 22 be? 23 And if you give me a little time, Α. 24 I'll try to think of his name. 25 Certainly. Q. A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 Which won't be momentarily. I have a Α. 2 name problem. He's no longer with the University. 3 Q. Do you know what his expertise was or 4 was he with preventive medicine or --5 He -- his area of expertise is Α. 6 pulmonary medicine. 7 Okay. Q. 8 And did you know why your colleague, 9 your former colleague here at the medical center 10 gave them your name? Did he have a specific 11 reason why he recommended you, Dr. Schaffner, to 12 talk with Mr. O'Tuel's firm?

13 A. My memory is a bit dim on that, but I 14 think it was because they had an infectious 15 disease question in mind. 16 Q. Other than the work that you have 17 done for Mr. O'Tuel's firm in the tobacco 18 litigation, have you provided expert testimony in nontobacco litigation? 19 20 Α. Yes. 21 On how many occasions have you been Q. 22 retained to provide expert testimony in 23 nontobacco-related litigation? 24 I couldn't give you a number. It's 25 -- I'd call it kind of my night job. A. WILLIAM ROBERTS, JR. & ASSOCIATES 35 1 How long have you held this night Q. 2 job, if you will? 3 I must have begun, oh, 15 years ago, Α. 4 or thereabouts. 5 Q. Do you maintain a list anywhere of 6 the actions for which you've provided expert 7 testimony in the past? I've tried to provide a list for 8 Α. 9 those at your request, I think, of those instances 10 in which I have either been deposed or given 11 testimony. I've already told you about the 12 somewhat casual nighttime filing system. The 13 finances are reported rigorously to the Internal 14 Revenue Service, but then the rest of that 15 material, I don't need to keep, so this is the 16 list that actually, I think I provided first to Mr. O'Tuel, and he's -- I must have had part of it 17 18 handwritten or something, he's reformatted it, so 19 it looks better than the list I gave him. And 20 that's back since -- I don't know how far back it 21 goes. 22 I don't know either. Ο. 23 '92, if memory serves. Α. 24 Okay. We'll go ahead and mark what's 25 entitled William Schaffner, MD testimony, it's a A. WILLIAM ROBERTS, JR. & ASSOCIATES 36 3-page document with 34 entries on it, as 1 2 Schaffner Exhibit 2. 3 (Whereupon, the above-mentioned 4 document was marked Exhibit No. 2.) 5 BY MR. JEKEL: 6 I'm going to hand you Exhibit No. 2, 7 and if you can, Dr. Schaffner, can you tell me by 8 number if your testimony involved any questions 9 concerning cancer, be it lung cancer or some other 10 cancer? 11 I don't believe cancer was ever Α. 12 involved in these cases. 13 Q. Okay. In the Neri cases -- by the 14 way, is Neri listed on there? 15 Neri is not on here, so I guess I 16 haven't provided deposition testimony in that case 17 or my files didn't show it. 18 Do you gentlemen know whether he did Q. 19 give a deposition in those actions, Neri? 20 MR. LATHAM: I have no idea MR. JEKEL: You don't know, Mr. 21

```
22
      O'Tuel?
23
                   MR. O'TUEL: He did not.
       BY MR. JEKEL:
24
25
                  But it's your recollection none of
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
1
       these actions involved a question of lung cancer?
             A. I don't believe lung cancer, and to
      my best memory, cancer of any kind played a role
 3
 4
       in any of these cases. I'm an infectious diseases
 5
       doctor. These involve by and large issues of
 6
       infection.
 7
                   Can you identify just by number those
             Q.
8
       cases that may have involved infectious diseases
9
       of the respiratory system?
                  This stretches my memory. I can't
10
             Α.
11
       recall the subject of each and every one of these.
12
             Q. Okay.
13
                   But I don't believe that a
             Α.
14
       respiratory infection was the principle issue in
15
       any of these cases, to the best of my memory.
16
              Q. Any tuberculosis that you recall?
                  Tuberculosis was part of the issue in
17
             Α.
18
       No. 9, and that's the only one that I can recall
19
       that tuberculosis played a role in it.
20
             Q. Of the 34 items that are on Exhibit
21
       No. 2, do you know percentagewise on how many of
       those items you were retained by a defendant
22
23
       versus a plaintiff?
24
             A. I'd say plaintiff about 10 to 15
25
       percent of these.
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                  Do you maintain copies of any of the
1
       deposition and/or trial testimony that you've
 2.
 3
       given at your office?
 4
             A. No. When things are finished, I
 5
       discard those things, as I said.
             Q. Do you know which of these actions
 6
 7
       you may have provided trial testimony in as
8
       opposed to deposition?
9
                  That will be hard. Let's think. No.
             Α.
       2 went to trial. No. 6 went to trial. No. 9 went
10
       to an administrative hearing before a judge. I
11
12
       believe No. 16 went to trial. Well, maybe not. I
13
       can't remember. Oh, I don't know about 16. I
       think 24 went to trial. This is hard.
14
15
             Q. Just to the best of your
16
       recollection, Doctor.
             A. No. 25 went to trial where I was not
17
18
       an expert witness. I might remark I was a fact
19
       witness.
20
                  You were a treating doctor in that
             Q.
21
       case or --
22
                  Not exactly. It was a suit against
23
       Vanderbilt University about some events that had
       taken place, and I was party to the discussions
24
25
       that led to decisions that Vanderbilt did one
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
1
       thing or another, and I had to testify to that.
 2
             Q.
                  Okay. Very good.
                   That's about the best I can do.
             Α.
```

Thank you, sir. 5 Again, I want to refer back -- well, we'll get to Exhibit No. 1 in just a minute. I 6 7 have a copy of your CV dated June 17, 1998. This copy has some highlighting on it that I put on 8 9 there, but since you don't have a copy, why don't 10 we go ahead and mark this as Schaffner 3. 11 (Whereupon, the above-mentioned 12 document was marked Exhibit No. 3.) 13 BY MR. JEKEL: 14 Q. Take a minute to review what I have 15 marked as Exhibit No. 3. I just want to make sure that it's up to date and if you have any new 16 17 publications, texts, things of that matter that 18 would be added on there, that we go over those. 19 Well, this is dated June 17th, 1998, Α. 20 and I know there have been changes since then. 21 Q. Maybe at a break you could get me a 22 more up-to-date version, and we could just make it 23 an exhibit to the deposition, would that be 24 acceptable? MR. LATHAM: We've got an updated one 25 A. WILLIAM ROBERTS, JR. & ASSOCIATES 40 1 that we can provide. MR. JEKEL: Can I take a quick look 3 at it? 4 MR. LATHAM: Sure. MR. JEKEL: We've got one here marked 5 6 June 12th, 2000. Just want to make sure I see all 7 the new stuff. 8 MR. LATHAM: Could we take a quick 9 break while we look at this? MR. JEKEL: We'll go off the record 10 for just a minute, gentlemen and ladies on the 11 12 phone. 13 (Discussion off the record) MR. JEKEL: We're going to substitute 14 15 Exhibit No. 3, which was previously marked as the 16 June, 1998 CV with the June 12th, 2000 CV. Has 17 anybody got a problem with that? 18 MR. LATHAM: Fine with me. I'll take 19 the sticker, madam court reporter, and place it on 20 the new one. Good enough? BY MR. JEKEL: 21 22 Dr. Schaffner, is the CV that we Q. 23 marked June, 2000 up to date? 24 Yeah, reasonably. Α. 25 Are there currently publications that A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 are not reflected in your CV which you are working 2 on presently or submitted for publication? 3 Actually, there may be a -- yeah, I 4 think there is on page 27, there's probably one 5 more after that, some publication and patient care having to do with influenza. 6 7 Q. Okay. 8 That's the only one I can recall. 9 The only other thing that's a slight change here 10 is that in front of the CV, in the Professional 11 Societies on page 3, No. 4, Infectious Diseases 12 Society of America, I've had a lot to do with that

13 organization, and I've just been elected a 14 national counselor to that, you know, to the 15 board. 16 Very good. Q. 17 Α. Thank you. 18 Are those the only changes that you Q. 19 think need to be made today to your CV? 20 I believe those are the only ones, 21 yeah. 22 Okay. Very good. Q. 23 You are a medical doctor, Dr. 24 Schaffner? 25 Α. Yes, Mr. Jekel. A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 And you obtained your medical degree Q. 2 from Cornell? 3 Cornell University Medical College, 4 yes. 5 And you are board certified in 6 internal medicine, infectious diseases, and 7 preventive medicine? 8 Α. Yes. 9 I'd like to just break those down, if Q. 10 we could. Quite simply, give us a simple 11 explanation of what is internal medicine. 12 Internal medicine is the -- relates 13 to the understanding of diagnosis and care of 14 patients who -- adults who have diseases that are 15 not taken care of through surgery. That would be 16 the easiest way to describe it. 17 Q. Would that include patients with 18 coronary heart disease? 19 Α. Yes. 20 Would it include patients with other Q. 21 vascular-type diseases? Yes. It could, to the point that 22 23 they might need surgery, for example, but a patient with diabetes might have vascular disease 24 25 that might fall under the regular care of an A. WILLIAM ROBERTS, JR. & ASSOCIATES 43 1 internist. 2 Q. Hypertension? 3 Α. Surely. 4 Do you currently actually see Q. 5 patients on a day-to-day basis with regard to your 6 practice in internal medicine? 7 I see patients on rotation as an 8 infectious diseases consultant. Obviously, a lot 9 of those patients are patients of other internists, and many are surgical patients, but $\ensuremath{\mathsf{I}}$ 10 11 don't function as a general internist. 12 Q. Okay. When was the last time you 13 actually practiced internal medicine? 14 Generally internal medicine, that would be through about the mid 1980s. Well, I 15 16 think I can tell you more specifically because --17 It's in your CV? Q. 18 Well, only by inference. Hold on a 19 moment. 20 Until sometime in 1982 when I was 21 asked to chair the Department of Preventive

22 Medicine, and at that point, because there's just so many hours in the day, I had to give up my 23 practice of general internal medicine. 24 25 So when you see patients on rotation A. WILLIAM ROBERTS, JR. & ASSOCIATES now, can you tell me what that includes? Will you 1 prescribe treatment for those patients? 3 Α. Yes. 4 Will you prescribe testing for those Q. 5 patients? 6 Surely. 7 Will you prescribe follow-up care for 8 those patients? 9 Yes. And perhaps just not to be a 10 stickler, but we might refine the word prescribe, since most of my practice is consultative 11 12 practice, we offer suggestions to the primary care 13 physicians in all of those areas, but they have 14 the ultimate responsibility. When I admit 15 patients myself, and I occasionally rotate on the 16 admission, the infectious disease admitting 17 service, then that would pertain. 18 Q. So is it fair to say that currently 19 your internal medicine practice is limited to 20 those types of patients you may see while you're 21 on rotation? 22 Α. Surely. 23 Yes. 24 Q. Now, you're board certified in 25 infectious diseases. And, you know, that sounds A. WILLIAM ROBERTS, JR. & ASSOCIATES 45 to me like it covers an awful lot of ground. you give me a short explanation of what your 2. 3 day-to-day practice in infectious diseases really 4 entails? Infectious diseases in this context 5 Α. is one of the subspecialties of internal medicine, 6 7 and you get further training in that area, and my 8 current practice in infectious diseases occurs 9 when I have the responsibility for the infectious 10 diseases consult and the infectious disease 11 admitting service at the Vanderbilt University 12 Hospital, and I do that in the context of having 13 infectious disease fellows and residents and 14 occasionally students with us, so it's both a 15 service and a teaching service. It's quite 16 typical of academic medical centers in that 17 regard. 18 But you actually admit and treat Q. 19 patients under your infectious disease practice 20 here at the hospital? 21 Yes. The various subspecialties, 22 cardiology, pulmonary medicine, kidney disease, 23 all have admitting services at the Vanderbilt 24 Hospital, so if the patient's illness falls into 25 that category, principally, obviously, they can A. WILLIAM ROBERTS, JR. & ASSOCIATES 46 1 have things and other illnesses simultaneously, 2 but one of the physicians in the appropriate specialty would be their admitting doctor, and I

fill that role when it comes to infectious 5 diseases when I'm on rotation. 6 Q. Now, you're also the Chairman of the 7 Department of Preventive Medicine here at the University, and you are board certified in 8 9 preventive medicine, correct? 10 Α. Yes. 11 Q. Tell us a little bit about what --12 what is the goal of preventive medicine? 13 A. Well, generically speaking, the name 14 is self-evident. It teaches the discipline and 15 does research in the discipline that tries to 16 identify risk factors for disease, and it uses a variety of interventions to try and prevent 17 18 disease. This can be expressed on an individual 19 basis, an individual patient with their physician, 20 or when extended to the community, it blends into 21 public health. 22 Right. So as preventive medicine Ο. 23 relates to lung cancer, what would the goal be in 24 that regard? Would it not be to get people to 25 stop smoking? A. WILLIAM ROBERTS, JR. & ASSOCIATES 47 1 Actually, I guess the first goal 2 might be to prevent people from starting smoking, 3 and then to stop smoking, and since there are 4 other things that are predisposing factors to lung 5 cancer, you would try to make sure that, for 6 example, they, if they work in the asbestos 7 industry, that the occupational standards that 8 they have for precautions there are fulfilled and 9 the like. 10 Doctor, do you have an opinion in the Q. absence of cigarette smoking why their exposure to 11 12 asbestos can cause lung cancer? 13 A. I don't. How much of your work as the Chairman 14 Q. 15 of the Department of Preventive Medicine here at 16 Vanderbilt is spent trying to get kids and adults 17 to stop smoking or not begin smoking? 18 Basically, none, because that 19 activity in our medical center, it's my 20 understanding is being led by some of the 21 oncologists. 22 And those would be people at the Q. 23 Ingram Cancer Center? 24 A. I'm sure they're affiliated with the 25 Ingram Cancer Center, yes. A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 Because you don't actually treat 2 patients with lung cancer here at Vanderbilt, do 3 you? 4 At the Vanderbilt University Α. 5 Hospital? 6 Yes. Q. 7 Oh, certainly. 8 Do you treat them for their lung 9 cancer or do you treat them for other problems 10 they may have? 11 I beg your pardon? I may have 12 misunderstood your question. By you, you meant me

```
13
       personally?
                   You, Dr. Schaffner, personally.
14
             Q.
15
                   Rather than in the southern parlance,
16
       y'all?
                  Y'all, that's right.
17
              Q.
18
                   I do not treat, so let me clarify.
              Α.
19
                   Thank you.
20
                    I do not specifically admit patients
              Α.
       with lung cancer for reasons of their lung cancer,
21
22
       and I do not consult on them regarding their
23
       therapy. If patients with lung cancer sometime
24
       during the course of their illness develop or are
25
       considered to possibly have an infectious
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       complication, that might be my role in their care.
              Q. Okay. So is it also true then,
 2.
 3
       you've not done any research or published any
       articles as it relates to health and smoking?
 4
 5
              Α.
                  One might be considered within that
 6
       category broadly construed. When I was still a
 7
       very junior faculty member in my figurative short
       pants, I had a relationship with a chemist here at
 8
9
      Vanderbilt, and we did a series of studies on
       whether certain materials could be detected in the
10
11
      breast milk of nursing mothers. One of those
12
       studies, in his laboratory he determined nicotine
13
       concentrations, but that's, I think, as close as I
       can come to the arena that you've described.
14
15
             Q. Would you be able to identify that
16
       article on your CV?
17
             A. This will take a moment.
18
                  I understand. I know it's a long
19
       list.
20
                  It would be No. 45 on page 14.
                  Thank you. Do you know if that was a
21
              Q.
22
       peer review journal?
23
             Α.
                   You bet.
2.4
                   I'm sorry?
              Q.
25
              Α.
                   You bet.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                  Do you -- I don't recall, I looked
 1
       through it a while back, but do you have journals
 2
 3
       for which you are on the board to review articles?
 4
             Α.
                   Yes.
 5
                    I don't know if I've listed them on
 6
       the CV. I can't remember that.
 7
                  I thought I saw something, but it may
       have been somebody else. Can you just identify
 8
 9
       the journals for which you perform that function?
10
              A. Well, you know, you perform some on a
11
       more or less regular basis and then some are
12
       pretty rare, but I would include among them the
13
       New England Journal of Medicine, JAMA, J-A-M-A,
14
       the Annals of Internal Medicine, Journal of
15
       Infectious Diseases, Clinical Infectious Diseases,
16
       Infection Control in Hospital Epidemiology, the
17
       American Journal of Epidemiology, European Journal
18
       of Clinical Microbiology, and Infectious Diseases,
19
       journal called Infection, American Journal of
20
       Tropical Medicine Hygiene, and then others from
21
       Pediatric Infectious Diseases Journal and others
```

```
22
       that you get asked to review manuscripts from time
23
       to time.
                    Just for the benefit of those folks
24
25
       participating by the telephone, article No. 5 on
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
       Dr. Schaffner's CV is entitled "Determination of
 1
       Nicotine Concentrations in Human Milk" from the
 3
       American Journal of --
 4
              Α.
                    Diseases of Children.
 5
                    Diseases of Children, 1976 with a
 6
       Ferguson.
 7
                    Do you recall whether that article
 8
       determined that the source of the nicotine in a
 9
       mother's breast milk was from cigarette smoking?
10
                    It's been a long time, but I believe
11
       we had some nonsmoking mothers, some who smoked a
12
       little, and some who smoked more, and I believe
13
       they're along that gradient, there was more
14
       nicotine discovered in the breast milk, I believe.
15
       That's a crude summary of the results.
16
              Q.
                    All right.
17
                    But I haven't looked at that article
              Α.
18
       in ages.
19
                    Okay. I won't ask you any more about
20
       it.
21
                    In your position here at Vanderbilt,
       do you teach medical students?
22
23
              Α.
                    Yes.
24
              Q.
                    Currently what courses are you
25
       teaching or classes or lectures are you giving?
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                        52
                    It's, you know, medical school
       teaching doesn't always happen in the structure of
 2.
       a course, but there is a required course in
 3
       preventive medicine for which I have titular
       responsibility, and with a course director we
 5
       design that course. I give talks in that course
 6
 7
       having to do basically with infectious diseases.
 8
       I talk to the students in other courses and on
 9
       other occasions about other aspects of infectious
       disease often having to do with infection control,
10
       preventing transmission of infections from patient
11
12
       to patient, and from indeed patients to
13
       themselves, and then when we see patients, when I
14
       perform my clinical service responsibilities, we
15
       often have medical students with us at that time
16
       and provide them an introduction to clinical
17
       infectious diseases practice, but that's not in a
18
       structured classroom environment. That's clinical
19
       as it's commonly known, bedside teaching.
20
                  Right. How much of your time do you
              Q.
21
       spend on the clinical aspects as opposed to more
22
       the scholarly aspects?
23
                    Of my total professional life?
24
                    Of your total professional life.
25
                    As you may have been able to discern,
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       we sometimes do two things at the same time.
 2
       You're teaching -- you're taking care of a
       patient, but you're also teaching at the bedside,
```

so it's hard to parse those things. Q. I would consider that clinical though 5 6 for purposes of my question. 7 A. So you're mostly interested in the stand-up lecture room seminar teaching format for 8 9 this purpose? 10 Q. Research and writing as opposed to 11 being with a patient at a bedside on rounds, et 12 cetera. 13 In addition to that, I have 14 administrative duties as Chairman of the 15 Department, and so which piece were you just --16 Q. I'm more interested to determine how 17 much time you actually spend with patients, either 18 be it bedside teaching, on rounds, et cetera. 19 Α. Yeah, okay. Well, I'm on service 20 three or four rotations a year. Each of the 21 rotations is about 3 weeks, and during that period 22 I'd say 70 to 80 percent of my day is devoted to 23 taking care of patients. 24 In the last year, can you tell me how 25 many patients that you've seen or treated that had A. WILLIAM ROBERTS, JR. & ASSOCIATES 54 1 lung cancer, even though you weren't treating them 2 for lung cancer? I don't think I can tell you that. 3 Α. 4 Was it more than one? Q. 5 Was there at least one? 6 Α. I'm loath to say there were none. It 7 was not a huge number, not a large number. 8 Q. But it was at least one? 9 I can't remember. How many patients in the last year do 10 you think you've seen or treated that had coronary 11 12 heart disease? 13 Well, we have a very sick population at Vanderbilt, so some of them have underlying 14 15 diseases, and many of them would have had some 16 degree of underlying coronary heart disease or 17 and/or hypertension. 18 Are those patients rather that you Q. 19 actually treat? 20 A. If you mean are those patients for 21 whom I have primary responsibility as a physician, 22 the answer would be no. Again, I would be seeing 23 those patients principally in consultation. Now, 24 on occasion, a patient with coronary artery 25 disease and an infection will be admitted to the A. WILLIAM ROBERTS, JR. & ASSOCIATES hospital, and if I am the admitting doctor, I 1 2 would have principal responsibility for them, but 3 it would be -- the modus operandi of that would be because they have infection. 5 Can you tell me of the patients within the last year at Vanderbilt that you have 6 7 seen that had underlying coronary heart disease, do you have any estimation as to how many of those 8 9 patients were smokers or smoked within the last 10 five years? 11 I would have no answer for that Α. 12 beyond saying some.

13 When you were practicing internal Q. 14 medicine, if a patient presented and had some 15 coronary heart disease, is one of the things you 16 would ask them is, do you smoke? Obtaining a smoking history would be 17 18 part of the routine history of every patient. Okay. Even an infectious disease 19 20 patient? 21 You asked me that question, the Α. 22 former question in the context of my general 23 internal medicine practice, and --24 Q. Assuming, yeah. 25 And so the answer was, it's part of Α. A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 the routine medical history of every patient you see in general medical practice. Smoking history 2 3 becomes more or less relevant in infectious diseases depending upon first the underlying 5 circumstances that bring the patient to the hospital, and then whether or not the patient's 6 7 illness involves the respiratory tract or some other aspect, so it might or might not be germane. 8 9 Now, Dr. Schaffner, you're not a Q. 10 cardiologist, are you? 11 I'm not a cardiologist. 12 And you're not a pulmonologist, are 13 you? 14 Α. Neither. 15 Q. And you're not an oncologist? 16 Correct. Α. 17 Do you consider yourself an Q. 18 epidemiologist? 19 Α. Yes, small e. 20 Small e. And in what aspects or --21 what's your practice as it relates to 22 epidemiology? 23 Α. I'm a long-term consultant to -- let 24 me back up. 25 I spent part of my training at the A. WILLIAM ROBERTS, JR. & ASSOCIATES 57 Centers for Disease Control fulfilling my 1 2 Selective Service obligation and was introduced to 3 the principles of epidemiology and epidemiologic 4 field practice, investigating outbreaks of 5 disease. I have been, when I returned to 6 Vanderbilt, I became a consultant to the Tennessee 7 Department of Health, our state health department, 8 and I have remained a very, very active consultant 9 with them for the subsequent, I guess, must be 10 close on to 30 years. In that context, I have 11 been very involved in communicable disease control 12 activities which often have involved investigating 13 outbreaks of disease, and that's where we apply 14 epidemiologic principles. 15 The other arena in which I function 16 as a small e epidemiologist is for that same 17 period of time, since I have returned to 18 Vanderbilt, I have been the director of the 19 medical center's Infection Control Program, which 20 is also called Hospital Epidemiology where we try 21 to keep the infectious risks to patients,

22 visitors, and personnel as low as possible. Q. Dr. Schaffner, would you agree with 23 24 me that as it relates to questions of screening, 25 diagnosis, and treatment of lung cancer, that A. WILLIAM ROBERTS, JR. & ASSOCIATES 58 1 those issues are better left to experts in cardiology, pulmonology, and oncology? MR. LATHAM: Object to the form of 3 4 the question. 5 THE WITNESS: I think all of those disciplines can make contributions to those areas. 6 7 But I don't know that we want to -- one would 8 "leave" them to just those and in particular the 9 issue of screening, which although it can involve 10 all those arenas, rests on epidemiologic 11 principles. 12 BY MR. JEKEL: 13 Q. Let's just talk about treatment of lung cancer. Do you think you, as an expert in 14 15 internal medicine, infectious diseases, and preventive medicines, have more expertise as a 16 17 cardiologist, pulmonologist, or oncologist in how 18 to treat a lung cancer? 19 Α. No. 20 Other than the article on nicotine Q. that you pointed out, have you been involved in 21 any other research or publication of an article or 22 23 book that dealt with cigarette smoking and/or lung 24 cancer? 25 No. I don't think so. Α. A. WILLIAM ROBERTS, JR. & ASSOCIATES During your work for Mr. O'Tuel's firm, have you ever asked to review any internal 2. 3 documents from RJR or any other tobacco company to 4 see their research on the effects of cigarette smoking and/or nicotine? 5 6 A. I have not. 7 My expertise hasn't related to that. 8 The questions they've asked me haven't gone to 9 those questions. Q. Have you ever designed a Medical 10 11 Monitoring Program of any sort? 12 A. Could you help me by defining medical 13 monitoring a little bit for me? Well, let's -- a screening program 14 15 for a certain disease over a long period of time 16 covering a large population first. 17 Yes. Α. Okay. As it relates to screening, 18 Q. 19 what types of diseases or illnesses have you been 20 involved in putting into place a long-term 21 screening program? 22 They're all infectious diseases. 23 Did you do any of that work for the 24 CDC? 25 I don't believe while I was an active A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 duty public health service officer at the CDC I can recall putting into place a screening program in the course of my two years there.

When you are designing, can you tell Q. 5 me at least how many of these screening programs 6 you've designed over the course of your 7 professional background or history? Most of them have occurred in the 8 9 context of first my work as the hospital epidemiologist, the director of the Infection 10 11 Control Program, and let me give you a quick 12 example. From time to time we have an infection 13 problem within the institution, perhaps with a 14 bacteria that is resistant to multiple antibiotic 15 agents, for example, in an intensive care unit. 16 In addition to investigating the reasons for that, 17 we might think it's important enough to identify 18 all individuals, all patients who are infected, 19 even though they may not yet be "a case," they may 20 not manifest symptoms, so we would conduct a 21 screening program using bacterial cultures of all 22 the patients in the intensive care unit, and we 23 might run that for a period of time for all new 24 admissions or we might periodically screen 25 everyone who's in the unit, let's say once a week, A. WILLIAM ROBERTS, JR. & ASSOCIATES 61 for example. And so many of them have been in 1 2 that context. We might indeed screen some medical 3 personnel also to see if they were carriers of the 4 5 organism that we were interested in, and then 6 analogously from time to time in my work with the 7 Tennessee Department of Health, we conducted 8 similar screening programs, usually related to an 9 acute communicable disease outbreak. 10 I hate to make it too simple, but is there a checklist or a list of items that you, 11 12 when you are developing a screening program, that 13 you will go down and try and define or put limits 14 on before you implement a screening program, for 15 example, how many people are we going to screen? 16 Are we just going to screen people in ICU, or do 17 we need to screen people outside? I'm just trying 18 to get the process by which you develop and 19 implement the screen. 20 Α. Yeah, you would always do something 21 like that. 22 Can you walk me through the steps Q. 23 that you, Dr. Schaffner, may take in developing 24 and implementing a screening program? 25 Well, very quickly, and I wouldn't A. WILLIAM ROBERTS, JR. & ASSOCIATES want to be limited to this in an absolute way, 1 2 because it's off the top of my head, but you would 3 have to have the problem reasonably well defined. 4 Q. Okay. 5 You would like to identify the A. 6 population at risk, which is the target for the 7 screening program. You would like to have a 8 modality that you were going to use to screen, 9 what's the screening mechanism that you're going

Q.

culture?

Would that be like a bacteria

10 11

12

13 Such as a bacterial culture. Α. 14 All right. I'm sorry. Q. 15 You would figure out exactly, for Α. 16 example, to follow that example along, which 17 anatomic sites you would screen. 18 All right. Q. 19 You would make sure that the method Α. 20 you're using is sufficiently sensitive and specific to do the task. You would like to have 21 22 some idea of how long this screening program is 23 going to go on. You would wish to make sure that 24 in this instance the laboratory is ready to 25 process the specimens in an efficient, timely, and A. WILLIAM ROBERTS, JR. & ASSOCIATES accurate fashion. There would be issues of cost. 1 You would have to be clear in your own mind what 2. 3 to do with those tests that are found to be positive as well as those that are found to be 5 negative, and you would have to be sure that you 6 had some goals that resulted in a net benefit from 7 doing the process. 8 Let's just take a look at that last Q. 9 one, the goals, the net benefit. What do you look 10 at in terms of that? Can we help the people with 11 the disease? Is that what the net benefit is? 12 Well, if we're pursuing my little 13 example, it might be to prevent transmission of 14 this bug to others, and so if you determine that 15 someone had a positive culture, you could 16 institute the appropriate isolation procedures, or 17 you might move all the positive people to one area 18 of the intensive care unit, patient placement, 19 that's called, you could institute education so 20 that the nurses and others who care for that 21 patient, the physicians are made aware of the fact 22 that that person is positive and they take not 23 only their routine, we hope rigorous aseptic 24 practices, but they are even more aware of their 25 importance, so each instance has a different set A. WILLIAM ROBERTS, JR. & ASSOCIATES of goals, but you have to have them clearly in 1 2 mind when you begin. 3 Q. As it relates to lung cancer, do you 4 think that extending someone's life expectancy 5 with lung cancer, be it a year, two years, six 6 months, would be a net benefit to that individual? 7 I think that that's likely a net 8 benefit if you could be sure that the process 9 would do that, certainly. 10 Q. Is there a minimum limit as it 11 relates to extending an individual with lung 12 cancer's life that you would require like it 13 wouldn't be a benefit unless we get them three 14 more months or a year or something like that, or 15 is one day sufficient? 16 A. Well, those are always tough 17 questions and are the things that you consider at 18 the time. I don't think that there is a rule out 19 there that you can grasp on. 20 Q. But in general, extending one 21 person's life would be a net benefit to that

22 person? 23 No, I wouldn't say that as a general Α. 24 rule. You haven't put any time limits on it, and 25 you haven't said anything about the quality of A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 life. We have people in the intensive care unit who are mortally ill, and I think, for example, and in discussions with their families, physicians 3 4 now in agreement with everybody discontinue 5 intensive therapies because even though one can prolong life, the life is devoid of meaning and 6 7 indeed might cause anguish for survivors. 8 So a real limitation you put on 9 extending a person's life as part of that quotient 10 would be the length of extending the person's life and then the quality of that person's life during 11 12 the time it's extended? 13 Indeed, those would be important Α. 14 considerations. It might not be the only 15 considerations, but they're certainly very 16 important ones. 17 Is there a text or a publication that Ο. 18 you believe provides a fairly good discussion on 19 screening programs, as you've discussed, 20 implementation and design of a screening program? 21 I think there are numerous 22 monographs, books, texts, and I'm sure some 23 journal articles on the principles of screening 24 today. They're in most of the clinical 25 epidemiology texts and the general epidemiology A. WILLIAM ROBERTS, JR. & ASSOCIATES 66 textbooks. Is there any one that comes to your 2. Q. 3 mind as being authoritative or the one that if you 4 went into the library now would be the first one 5 you went for? No. The first one I went for might 6 Α. 7 be the first one on the shelf, so -- I don't think 8 there is a single authoritative text. 9 And I just want -- a lot of this, Dr. 10 Schaffner, is just to make sure exactly what we 11 can expect from you at trial some day, but any 12 clinical epidemiological texts or a similar book 13 that discussed screening programs would be 14 sufficient. I just want to make sure you don't 15 come at trial with a book on clinical epidemiology that discusses all of these screening program 16 17 requirements that you didn't disclose to me today. 18 That's a --Α. 19 Do you know, is there such a book in Q. 20 your mind? 21 There is no single book in my mind. 22 I have not identified one for you here today. 23 Okay. Or for Mr. O'Tuel? Q. 24 Oh, not for Mr. O'Tuel either. Α. Very well. Then I feel comfortable. 25 A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 Have you done any work for the United 2 States Surgeon General on any disease topic? Mr. Jekel, when I was a commissioned

officer in the United States Public Health 5 Service, we were sent in the field on the orders of the Surgeon General. That's the way it was 6 7 stated. But I don't think you mean that. Q. How rude of me. Outside of your 8 experience as a public health --9 A. -- commissioned officer in the 10 11 Public Health Service. 12 Commissioned officer in the Public Q. 13 Health Service, have you done any research or 14 worked with the Surgeon General's office? 15 You got to remember I was an 16 infantryman. We didn't know any of that. A. I have been a frequent consultant to 17 the CDC, but I don't believe I can recall an 18 19 instance where I have specifically been a 20 consultant to the office of the Surgeon General. 21 Okay. And when was the last time you 22 were a consultant to the CDC or on what issue, 23 topic, disease, if you will? 24 Well, the last time was July, I 25 think, and a group of us were asked to come back A. WILLIAM ROBERTS, JR. & ASSOCIATES 68 and to help the CDC think about and plan the 50th 1 anniversary activities of this program at the CDC, 3 which is train epidemiologists. It's called the Epidemic Intelligence Service. That wasn't 4 5 disease specific, and that was more fun than hard 6 work. 7 Sounds like a good group. Q. 8 But we're recipients of contracts and Α. 9 grants from the CDC either directly or now even more frequently through and in collaboration with 10 the State Health Department, and in that sense we 11 12 are frequently gathered with colleagues at the CDC 13 in planning conferences and the like. All of 14 those things have to do with communicable 15 diseases. 16 All right. Let's go over your report 17 a little bit now. Let me get you a copy in front 18 of you. 19 Now, I don't see a signature page on 20 this report. Did you sign any copy of the 21 disclosure? 22 Any version? 23 Excuse me. I don't -- perhaps we're Α. 24 not quite on the same figurative page. I don't 25 believe this is a report. I did not create a A. WILLIAM ROBERTS, JR. & ASSOCIATES 69 1 report and submit. 2 Q. It's -- you're right. Technically, 3 it's an Expert Witness Disclosure. Did you sign 4 the disclosure form, any version of the disclosure 5 form? 6 No. I was not asked to do that. 7 And is it fair to say that this is not a disclosure that you drafted sentence for 8 sentence, word for word? 9 10 Oh, for sure I have not done that. I 11 recognize my language in here, but certainly the 12 tone and stuff, because it's the product of

13 discussions with Mr. O'Tuel. 14 Q. Now, subject matter of your expert 15 testimony, I just want to take that first 16 sentence. "Dr. Schaffner will be offered as an 17 expert in the field of infectious disease and 18 medicine." Can you give me any more definition on medicine? Is that the whole ball of wax medicine 19 20 or a limited area there? 21 Is that your word? 22 Let's continue the sentence because I Α. 23 understand it perhaps a bit more in its entirety. 24 Okay. 25 I'll be offered as an expert in the Α. A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 fields of infectious diseases in medicine as they relate to the role of an infectious disease 2. 3 specialist in the diagnosis and treatment of infections of the respiratory system and 4 5 infectious disease processes in general. 6 Okay. Q. 7 I'll stand on that. Α. Q. 8 How does that relate to diseases 9 caused by cigarette smoking and lung cancer? 10 MR. LATHAM: Object to the form of 11 the question. That's confusing. Can disease be 12 caused by lung cancer? 13 BY MR. JEKEL: As it relates to a disease of the 14 Ο. respiratory system and/or lung cancer. 15 16 MR. LATHAM: Okay. 17 THE WITNESS: Would you restate the 18 question? 19 BY MR. JEKEL: 20 Yeah. What does that statement have Q. 21 to do with the medical monitoring class action 22 that the plaintiffs have brought here? What do 23 infections of the respiratory system have to do 2.4 with diseases that are caused by smoking and/or 25 lung cancer? A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 MR. LATHAM: Object to the form of 2 the question. It calls for a legal conclusion. 3 Subject to that, you can answer the question. 4 BY MR. JEKEL: 5 Q. Do you know what that means? 6 I think I know what it means, Α. 7 because --Did you write that sentence? Well, it goes on to the next 8 9 Α. 10 sentence. No. Q. That one sentence? 11 12 I didn't write that sentence, but I 13 didn't object to it. 14 Can you tell me what your understanding of that first sentence is, what 15 16 would that include as it relates to this case? 17 Well, permit me to go on to the 18 second sentence, which kind of, I think, extends 19 the thought and perhaps makes it a bit more 20 specific. 21 He, I, will testify regarding

22 infectious diseases in West Virginia and their 23 relationship to the plaintiffs' proposed Medical Monitoring Program. 24 25 Q. All right. A. WILLIAM ROBERTS, JR. & ASSOCIATES 72 1 Infectious disease and medicine as they relate to the role of an infectious disease 3 specialist in the diagnosis and treatment of 4 infections of the respiratory system and 5 infectious disease process in general. 6 Let's stop right there. Is lung 7 cancer an infection of the respiratory system? I'm not familiar enough with the 8 9 molecular biology of lung cancer to comment on the 10 role of oncogenic viruses and generation of that disease, and viruses thought broadly are within 11 12 the context of infectious diseases, but -- so if 13 you will permit me to exclude that notion -- I've 14 forgotten your question. Sorry. 15 Q. Is lung cancer, if you want to break 16 it down by type of cell, type lung cancer, we can 17 do that. In general, is lung cancer an infection 18 of the respiratory system? 19 A. In general, lung cancers are not 20 thought to be infectious diseases. 21 Okay. So the development of lung Q. cancer, the growth of tumors in the lung, that's 22 23 not part of the infectious disease process in 24 general, is it? 25 No. I think that that's a phrase Α. A. WILLIAM ROBERTS, JR. & ASSOCIATES 73 that's a generic phrase that's in there such that if we get into the discussion of an infectious 2. 3 disease, I can talk about the infectious disease 4 process. 5 Okay. Do you understand that the plaintiff's Medical Monitoring Program has sought 6 7 to test or screen for any type of infectious 8 disease of the respiratory system? 9 Well, I'm not sure that I have a very 10 clear idea of the actual structure and design of 11 the Medical Monitoring Program. I'm given to 12 understand in conversation with the attorneys here 13 that that's kind of still a work in progress, if 14 you will. 15 The issue is, isn't it, that whether 16 infectious diseases can complicate the diagnosis, 17 specific diagnosis of some of the diseases in 18 question. 19 Okay. And that's what you understand Ο. 20 your real role in this litigation to be? 21 MR. LATHAM: Object to the form of 22 the question. 23 BY MR. JEKEL: 24 To understand how the screening 25 program or monitoring program that the plaintiffs A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 have proposed may be complicated by the incidence 2 of infectious disease in the class population; is that fair?

That's pretty close, yes, I think Α. 5 that's pretty accurate. 6 Last sentence in that first paragraph 7 under Subject Matter of Expected Testimony. "Dr. Schaffner may also comment upon the " -- I'm 8 9 sorry -- "the opinions expressed by other 10 witnesses and/or additional evidence developed 11 before and during the trial to the extent they 12 relate to his area of expertise." 13 I noted a couple of expert reports in 14 the pile of materials you have in front of you, 15 one being the report of David M. Burns, MD. 16 Are you, as you sit here today, 17 prepared to discuss the opinions of Dr. Burns? 18 MR. LATHAM: Object to the form of 19 the question. Very overbroad. There's many 20 things in that document that don't relate to 21 medical screening at all. 22 MR. JEKEL: Yes. I'll limit it to 23 the medical monitoring aspect of Dr. Burns' 24 report. 25 THE WITNESS: I'm happy to discuss A. WILLIAM ROBERTS, JR. & ASSOCIATES 75 1 aspects of that, not each and every aspect because there are areas outside of my expertise and areas 3 where my area of expertise would not specifically 4 interact with elements of the proposed monitoring 5 program as recorded in this document. 6 BY MR. JEKEL: 7 All right. And we'll go through that Q. 8 in just a minute. Quite honestly, Dr. Schaffner, 9 it will move things along considerably if you think something is outside of your area of 10 expertise to just let me know and I will move on. 11 12 Thank you. 13 All right. Are there, or can you Ο. identify for me, Doctor, diseases that in your 14 15 opinion are causally related to smoking cigarettes 16 that mirror or could be confused with infections 17 of the respiratory system? 18 MR. LATHAM: Object to the form of the question. It's compound. Subject to that, 19 20 you can answer the question. 21 THE WITNESS: Could you restate the 22 question? I lost it in the exchange. 23 MR. JEKEL: That's all right. Maybe 24 she can read it for us again, or I can break it 25 down. Let's do it the easy way. A. WILLIAM ROBERTS, JR. & ASSOCIATES 76 1 BY MR. JEKEL: 2 Q. Dr. Schaffner, do you have an opinion 3 that certain diseases are causally related to 4 smoking cigarettes? 5 A. In a general way, yes. You are a medical doctor. In your 6 7 capacity as a medical doctor, would you agree with 8 me that cancer of the lip, mouth, and pharynx 9 could be caused by cigarette smoking? 10 That's -- I'm not sure about those. Α. 11 I'm not sufficiently acquainted. 12 All right. Well, let's, again, I'll Q.

-- I'm referring to Dr. Burns' report, page 3, 13 14 paragraph 7. And let's just -- of the diseases 15 listed in paragraph 7 of Dr. Burns' report, are 16 you in agreement on any of those items that you 17 believe cigarette smoking causes the human disease 18 identified? 19 I think cigarette smoking, if it's of Α. 20 sufficient dose and long enough can be generally, 21 because this is not my area of expertise, can be 22 generally thought of as being related to cancer of 23 the lip and the oral cavity and certainly to the 24 lung. I'm less aware of some of the other 25 details, although I'm generally aware, as I read A. WILLIAM ROBERTS, JR. & ASSOCIATES 77 1 down the list, also its association with cardiovascular disease and what we might call 2 3 chronic pulmonary disease. Bronchitis, emphysema, chronic airway obstruction, for example. 4 5 Q. And you refer to those as pulmonary 6 disease? 7 Chronic pulmonary disease, right. Chronic obstructive pulmonary disease. Bronchitis 8 9 is something more specific, but in a general way. 10 Now, of those I checked off six items 11 on here, of those six items that you and Dr. Burns 12 are in agreement that cigarette smoking causes, is 13 there an infection out there that could cause any 14 of these items? 15 MR. LATHAM: Object to the form of 16 the question. It misstates his prior testimony. 17 Subject to that, you can answer the question. 18 THE WITNESS: Are there infections 19 that can cause bronchitis and emphysema and chronic airway obstruction? 20 21 BY MR. JEKEL: 22 Yes. Ο. 23 Α. There are certainly infections that 24 can increase those symptoms, and it is thought 25 that, for example, simple whooping cough in A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 children can predispose them to adult bronchitis 2 and chronic pulmonary disease, for example. 3 Q. Would that be a child who had ever 4 smoked before? 5 A. I don't believe smoking played a role 6 in that. 7 All right. Let's talk about a 8 situation in this instance, we have a patient, he 9 presents with bronchitis, emphysema, COPD. That 10 patient has a smoking history of 10 pack years. 11 Would there be, in your opinion, an infection that 12 could be the cause of those symptoms or those 13 diseases? 14 MR. LATHAM: Object to the form of 15 the question. Very confusing. 16 Subject to the question, you can 17 answer. 18 MR. JEKEL: We'll let the doctor tell 19 us what's confusing and not the lawyers. You can 20 put your objection on the record, but Dr. 21 Schaffner is intelligent enough to tell me when

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22
       I'm not being clear.
23
                    MR. LATHAM: The objection stands.
                    MR. JEKEL: Certainly. You can just
24
25
       say, objection. You don't need to tell the
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       79
 1
       witness.
                    THE WITNESS: I'm not exactly clear
 3
       on what it is that --
 4
       BY MR. JEKEL:
 5
                   All right. Let's take this, we have
              Q.
       a patient; he presents with bronchitis. That
 6
 7
       patient has a smoking history of ten pack-year
 8
       history. Are you familiar with how we calculate a
 9
       pack year smoking history?
10
              Α.
                   Yes.
11
                   Do you know what a ten pack-year
              Q.
12
       smoking history is?
13
              Α.
                    I do.
14
                    What's your definition of a ten
15
       pack-year smoking history, just so we get it on
       the record and we're all not confused.
16
17
                   Pack a year for ten years.
              Α.
18
                   All right. Do you think that is a
              Q.
19
       sufficient smoking history to cause bronchitis?
20
                  That's not right.
21
                    Pack a day for ten years.
22
                    Pack a day for ten years.
              Q.
23
                    Now, shall we start again?
              Α.
24
              Q.
                    Yes. Is a ten pack-year history, in
25
       your opinion, sufficient to cause bronchitis or
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       80
 1
       emphysema?
                   Oh, that's something that I have no
 2.
 3
       opinion on because those are data that I don't
 4
                   Okay. What types of -- earlier you
 5
       said that there were infections that could -- I
 6
 7
       don't think you used the word exacerbate, but may
 8
       complicate the symptoms that we see from smoking
 9
       disease.
                    Oh, I don't think so.
10
              Α.
                    No? All right. Maybe I'm confused.
11
              Q.
12
              Α.
                    I think the comment I made that you
13
       are referring to has to do with when one screens a
       population for some of these diseases, in an
14
15
       attempt to pick up, for example, cancer of the
16
       lung, you will run into lesions that look like
17
       cancer of the lung, but in truth were caused by
18
       infections that the patient had previously.
19
                   Right. Now, and that, if we go back
              Q.
20
       to your expert report, is that what you mean --
21
       I'm looking on page 2, the first paragraph, the
22
       sentence beginning with the term, "Consequently,
23
       persons in West Virginia are more" --
24
             A. I have to find that. "Consequently,"
25
       in the middle of the paragraph.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       81
 1
                    "Persons in West Virginia are more
 2
       likely to have false positive radiographic
       studies." Is that kind of where we are now? I
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mean, you said they have lesions, they might show 4 5 up, they might look like tumors, but in fact they 6 were caused by an infectious disease. 7 A. Correct. Is that not what you are 8 9 communicating here in that sentence, somebody is 10 communicating here? 11 That's what this document was Α. 12 attempting to communicate. 13 Q. I got you. Now, you say positive 14 radiographic studies. What radiographic studies 15 are you including in your -- is that CT scans? 16 A. Well, it would be conventional chest 17 radiographs, but also CT scans and, again, it's my 18 informal understanding that the issue of PET scans 19 has also arisen in this context. 20 So that would include all of those? Q. 21 Α. Yes. 22 Is there a radiographic based study Q. 23 that you believe can differentiate a lesion in a 24 lung caused by an infectious disease versus one caused by or one that is truly a lung cancer? 25 A. WILLIAM ROBERTS, JR. & ASSOCIATES 82 1 I think that there is no single criterion that exquisitely completely distinguishes the two, but speaking generically, 3 if the lesion has some calcium in it, that makes 4 5 it much more likely to be a benign lesion probably 6 as a consequence of a prior infection, although 7 from time to time one can be fooled. It's 8 difficult in medicine to expect 100 percent 9 conformance. And which, the conventional X-ray, a 10 CT scan, and a PET scan of those, do you have an 11 12 opinion as to which is more likely to identify a 13 lesion as containing calcium? I don't. I would leave that specific 14 Α. 15 question to the radiographers. 16 Q. And what I would like to do is, what 17 is, other than your vast experience in treating 18 individuals with infectious diseases, what studies 19 are you relying on that support the proposition 20 that you can see lesions under radiographic 21 studies that appear to be lung cancer, the 22 beginning tumors of lung cancer, but are in effect 23 infectious diseases? Are there studies out there 24 that look at that? 25 I'm sure there are. I can't cite A. WILLIAM ROBERTS, JR. & ASSOCIATES 83 1 them to you chapter and verse. 2 Q. Okay. Let's talk --3 I suspect there are. 4 So as you sit here today, you cannot 5 identify for me one text or one peer review article that has looked at that specific issue? 6 7 That's correct. Now, let's talk about your personal 8 9 experience. Have you had an experience where you

Α.

saw in a patient on a radiographic study, X-ray,

CT scan -- do you review PET scans, by the way?

I don't as the PET scan, the official

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reader, but we have a PET scan here, and we run into them, as it were, from time to time in the care of our patients.

- Q. Right. So you're familiar really with all three of those types of radiographic studies?
 - A. Yes. Again, in a general way.
- Q. In your experience, have you been faced with the situation where you thought, A, this is an infectious lesion on somebody's lung where it turned out to be a cancerous tumor or vice versa, saw something that you thought was a cancerous tumor and then it turned out to be an
 - A. WILLIAM ROBERTS, JR. & ASSOCIATES

infectious lesion?

2.

1 2

- Well, I dare say occasions have Α. occurred where your -- my experience was such that when I saw the patient, I, in effect, in trying to assess the likelihood of whether a lesion was infectious or malignant or something else, that I thought it was more likely one than the other, and it turned out to be the reverse. I think it is more common to have a lesion etiology unknown that requires further investigation. I mean, our sense of -- well, I think it is fair to say, we develop -- I guess the three categories, this is likely to be non -- this is likely to be benign, possibly infectious. Oh, oh, this is likely to be malignant, or in the middle, huh, beats the heck out of me. Can't say.
- Q. And in which of those -- so even in your practice, you are faced with all three of those situations, correct?
 - A. Surely.
- Q. And what is your standard practice when you are faced with that, under all three of those scenarios, what is the next step?
- A. Well, the next step is often to get radiographic consultation. You might do further
 - A. WILLIAM ROBERTS, JR. & ASSOCIATES

radiographic definition if, in consultation with the radiographer, you think that that is useful.

- Q. I'd like to -- I'm not sure I understand that. In that situation, are you saying, all right, I've got a chest X-ray, I can't really tell from the chest X-ray, so let's go for a CT scan?
 - A. That would be a common approach.
- Q. I just want to make sure I follow you when you say we'll go back for more radiographic evidence. I'm sorry. Continue on. What might be the next step?
- A. Well, you would have to assess the patient's total circumstance, but let's for the moment talk about a patient who is otherwise reasonably well and has what we might say a reasonable life expectancy. We're not talking about assessing somebody who's morbidly ill. It then is common for one to want to make a more specific tissue diagnosis, and in consultation with the pulmonologist might assess not only the

22 characteristics of the lesion, but its location 23 and come to a decision about what to do next. Can it be reached by bronchoscopy, do you have to do 24 25 needle biopsy, for example? A. WILLIAM ROBERTS, JR. & ASSOCIATES 86 1 As it relates to location of the lesion, that's something that you can do just 3 through the radiographic studies, is it not? 4 Α. Largely, yes. 5 Now, do you or are you prepared to 6 talk about types of cell-type cancers, lung 7 cancers, and where they are most likely to appear on the lobes of the lung? 8 9 Α. No. I'm here as an infectious 10 disease doctor, and I mean, we could discuss that, 11 but I don't think that's useful because that's not 12 my area of expertise. I don't hold myself out as 13 an expert in that matter. 14 Okay. Now, assuming everything else 15 is equal, you mentioned a bronchoscopy as another 16 tool as to differentiate whether we are dealing with benign, possibly malignant, or possibly 17 18 infectious, the three categories that you gave me 19 earlier? 20 I don't think those are exactly the three categories, but it would be a diagnostic 21 modality which might next be employed, again, 22 23 depending upon the location of the lesion and the 24 likelihood that the bronchoscopy will actually 25 yield the material that can help you make a A. WILLIAM ROBERTS, JR. & ASSOCIATES 87 1 diagnosis. Let me ask you this, prior to this 2. Q. 3 stage or we've gotten to the three categories, can you look back and do a patient history to also help you in determining whether we fall into one 5 of these three categories? For example, were they 6 7 in an area where there was an epidemic of a 8 certain infection, have they been around certain 9 parts of the world, are they a smoker, how heavily are they a smoker, is there any medical history 10 11 that would help you differentiate in those 12 categories? 13 Certainly by the time we would get to Α. 14 this spot in the investigation of the patient and 15 the patient's problem, one would have taken a 16 medical history, which would include a past 17 medical history, a family history, a history of 18 prior exposure to tuberculosis and the like, and 19 you would have the contents of the earlier 20 investigation and perhaps some historical 21 information from the patient, and all of that 22 would be part of the information that you would 23 have as you looking at, for example, the X-ray, 24 where there was what we might call a spot on the 25 lung, helping you to try and assess the likelihood A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 of putting it in the likely benign, possibly 2 malignant, or indeterminate category along with

the physical characteristics of the lesion that

you have spotted. All of those, of course, are 4 5 helpful, but none of them are definitive. 6 What is the definitive mechanism, if Q. 7 there is one? 8 Α. Well, the definitive mechanism, of 9 course, is tissue. 10 And is that the -- as you go down Q. 11 your list of what you do and who you consult and all of the like, is that the last step, take a 12 13 tissue sample or a biopsy? 14 A. I'm not so sure it's always the last 15 step, but it is what you try to do to make a 16 definitive diagnosis, and sometimes that fails, 17 and sometimes there are other things that, for 18 example, if it's subsequently discovered we're 19 making this up as we go along here, that the 20 patient has another lesion, you might be able to 21 tap into that lesion. It's not as though every 22 time you get the tissue you always get a 23 definitive answer is what I'm trying to say. 24 mean, there are limitations to histopathology and 25 its interpretation. A. WILLIAM ROBERTS, JR. & ASSOCIATES 89 1 Depending on the actual tissue that 2 you get, you may not be able to make the 3 determination one way or the other? 4 Correct. Α. 5 Now, is it your understanding that 6 collection of tissue at a certain stage is 7 provided for or not provided for in the 8 plaintiffs' Medical Monitoring Program that's been 9 put forth in the Blankenship matter? Well, I haven't memorized it. 10 Α. Well, I think it --11 Q. 12 But, well, anyway. I'm sure -- why Α. 13 don't you direct me to that? 14 It's all right. We'll move on. 15 Again, I'm referring to Dr. David 16 Burns' report. All of the highlighting that we 17 see in here, is that yours? 18 Α. Yes. 19 Okay. Did the counsel or did the Q. 20 attorneys direct you to look at certain sections 21 of David Burns' report? 22 Α. They gave me this whole stack of 23 material, and I wouldn't have countenanced that. 24 I approached the material fresh. 25 They didn't tell you, take a good A. WILLIAM ROBERTS, JR. & ASSOCIATES 90 1 look at paragraph 9 in this Burns' report? 2 They did not. Α. 3 Q. Okay. 4 Α. Or anything like that. 5 All right. And why don't you just 6 take a few moments, I'm directing Dr. Schaffner's 7 attention to paragraph 32 and subparts of the 8 revised report of Dr. David Burns entitled 9 "Medical Monitoring," and I believe that is where 10 it is set forth, paragraph 32 really through 36, 11 and if you would just take a moment to familiarize 12 yourself with that.

13 Have you had an opportunity to review 14 that, Dr. Schaffner? 15 A. Yes. 16 We'll be referring to it off and on, Q. so I just wanted to give you that opportunity. If 17 18 I could direct you to page 17, paragraph C, I 19 guess it's the 3rd paragraph or the 3rd sentence 20 in paragraph ${\tt C}$ beginning, "The most promising of these scientific advances," have you found that 21 22 sentence? 23 Α. Yes. 24 "The most promising of these Ο. 25 scientific advances are rapid (single breath --A. WILLIAM ROBERTS, JR. & ASSOCIATES 91 1 whole helical) capital CT and computerized molecular analysis of airways cell markers." 2 3 First off, are you familiar with that 4 type of radiographic study? 5 Α. Only in the most, most general way. 6 Not really. 7 Okay. So can you, as you sit here Q. today, do you have an opinion as to whether that 8 9 modality -- can we call that a modality? 10 Α. Sure. 11 Is that modality likely to confuse a Q. 12 malignant tumor with a benign lesion? A. Well, I can't provide you here the 13 14 data on that. I have seen no data to suggest that 15 it can exquisitely distinguish those. 16 Q. Have you seen data to the contrary, 17 that it cannot distinguish those? 18 Α. No. The important data would be that 19 it can't. 20 Q. It can't. 21 I did note that you had, in your stack of materials, the article from which Dr. 22 Burns takes that statement. I don't think that 23 one is it. I know it's in here. I saw it, but I 24 25 just wanted to make sure while we're here we had A. WILLIAM ROBERTS, JR. & ASSOCIATES 92 1 it. There you go. 2 Is that not the paper or consensus 3 statement from the conference from which Dr. Burns 4 takes his information on the rapid CT? 5 Well, I'm a little -- I'm not so sure 6 I can tell you exactly because the folks who 7 participated much in this also published the study 8 in the Lancet, so I'm not sure that Dr. Burns 9 relied solely on this, but this does appear to be 10 the consensus statement of the First International 11 Conference on Screening for Lung Cancer. 12 And does the paper in which you have 13 that, does it not start off, "Lung cancer kills 14 more individuals than cancers of the breast, 15 colon, cervix, and prostate combined"? 16 MR. LATHAM: Is the question does it 17 say that? 18 THE WITNESS: Yes. It says that. It 19 must be limited to the United States. 20 BY MR. JEKEL: 21 Q. The Medical Monitoring Program that

```
22
       the plaintiffs have promulgated is going to be
23
       implemented in the United States, is it not?
24
                  No, no, no, no. I'm just curious
25
       because this is the First International Conference
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
       on Screening for Lung Cancer.
 1
              Q. Are you aware of data outside of the
       United States that indicates lung cancer does not
 3
 4
       kill more individuals than cancers of the breast,
 5
       colon, cervix, or prostate combined?
             A. I'm not. As I say, I'm not a cancer
 6
 7
       epidemiologist.
             Q. Moving on in that same, "Recent
 8
 9
       scientific advances create an extraordinary
10
       potential to develop a lung cancer screening
11
       program that would prevent untimely deaths of vast
12
       numbers of current or former smokers who remain at
13
       high risk despite smoking cessation. The most
14
       promising of these scientific advances are rapid
15
       (single breath -- whole helical) CT and
16
       computerized molecular analysis of airway cell
17
       markers."
18
                    You've not seen the data from which
19
       the conference relies upon in making that
20
       statement; is that correct?
21
                   I haven't seen the proceedings of
             A.
       this conference.
22
             Q. Okay. I can assume then that you did
23
       not participate in this conference?
24
25
             A. No. Certainly, I did not. It's
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       94
       likely that some of these data at least come from
       the Lancet study, but there may be others. I just
 2.
 3
       don't know.
 4
                   And the Lancet study says that low
              Q.
       dose CT can greatly improve the likelihood of
 5
       detection of small, noncalcified nodules and thus
 6
 7
       of lung cancer at an earlier and potentially more
 8
       curable stage, does it not?
 9
                   MR. LATHAM: Hold on a second. Read
10
       from the document and make sure he read it right.
                   THE WITNESS: Yes. That's the
11
12
       author's interpretation of their own studies, and
13
       as we will probably quickly agree, this is an
14
       early study, hasn't been confirmed by others, and
15
       it's done in a highly selected population.
16
       BY MR. JEKEL:
17
              Q.
                    I want to go over in detail your
18
       criticisms of this Lancet study. Under the
19
       author's interpretations again, the statement does
20
       go on, in all fairness. "Although false positive
21
       CT results are common, they can be managed with
22
       little use of invasive diagnostic procedures."
23
                   Do you agree with the author's
24
       statements there?
25
             A. I agree that that's what they
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       95
 1
       concluded.
                  Yes. Absent that's what they
       concluded, do you, Dr. Schaffner, agree with the
```

4 author's statement? 5 A. It's a generic statement, and I don't think it would apply to populations, many 6 7 populations outside the highly selected populations in which this study was done. This is 8 9 a highly -- this is a conventional early first 10 study investigating the modality of an agent. 11 It's not a study that tests this modality in 12 application to other populations. 13 Are you saying that they were only Q. 14 looking at people with lung cancer so that they 15 didn't have the potential or the problem of seeing 16 benign lesions and confusing them with malignant? 17 I'm just not sure I understand your statement. Well, I certainly didn't that say. 18 19 Well, you didn't say it in those 20 words. 21 No. I didn't say that in those words Α. 22 or any other words. 23 Q. Or any other words? All right. 24 What I said was, this is a highly selective population. It's only done in New York 25 A. WILLIAM ROBERTS, JR. & ASSOCIATES 96 1 City. They only selected people of a certain health status, those that could potentially withstand thoracotomy, and it was selected from, 3 even within New York City, only two locations, so 4 5 this is not a very generic study. 6 Q. Okay. 7 It's like many such studies, a first Α. 8 study, taking a look at an issue that requires 9 repetition in other populations to see whether the conclusions are generalizable or have to be 10 modified in substantial ways in other populations. 11 12 Do you have any other criticisms than 13 the ones you just identified for me with regard to 14 the Lancet study? 15 MR. LATHAM: Object to the form of 16 the question. 17 THE WITNESS: I don't offer them as criticisms. I just offer them as observations. 18 I'm not being critical of the authors. I am just 19 observing that it's an early, highly selected 20 21 study in a narrowly defined population, the 22 conclusions of which can't be generalized. It 23 calls for the application of similar methods in 24 other populations to see whether they can be 25 validated. It is not unusual in medicine to have A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 subsequent observations modify substantially the 2 conclusions in an initial paper and indeed to the 3 point that on occasion quite to the contrary results are discovered, so we wouldn't take this 5 as, if you will, the gospel. 6 BY MR. JEKEL: 7 Q. No, but in terms of preventive 8 medicine and getting individuals benefit, 9 extending someone's life with lung cancer, do you 10 think that the use of the low dose CT scan could 11 be justified solely based on this study? 12 Should we not use it just because you

13 think that this was the first study of a highly 14 local group of individuals where we only have a 15 health status, are those reasons enough to not 16 continue trying to develop the low dose CT scan in 17 terms of screening for lung cancer? 18 MR. LATHAM: Object to the form of 19 the question. THE WITNESS: I would emphasize that 20 21 in trying to investigate further the utility of 22 the low dose CT scan for the earlier and accurate 23 diagnosis of lung cancer, I think it ought to 24 continue to be used specifically in other control 25 trials in other populations. One would not make A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 public policy based on this study alone, not even 2. in New York City. BY MR. JEKEL: 3 4 Nor West Virginia, I assume, correct? Q. 5 Nor West Virginia, nor Missouri, nor 6 Tennessee, nor the state of Washington. 7 MR. LATHAM: Be a good time for a 8 break? 9 MR. JEKEL: Yeah. 10 (Recess) 11 MR. JEKEL: We're back on the record. 12 Have we got everybody? I'll assume that's a yes. If they've dropped off, we don't know, but we're 13 14 going to get started again. 15 ATTORNEY BY PHONE: Talking about 16 those of us who are on the phone, I assume that an 17 objection by one defendant applies to all? 18 MR. JEKEL: Absolutely. ATTORNEY BY PHONE: I was pretty sure 19 20 that was true, but I just wanted it on the record. 21 MR. JEKEL: Be good. 22 BY MR. JEKEL: 23 Going back to your report, the third Q. full sentence in the top paragraph, "Dr. Schaffner 24 25 is further expected to testify regarding the A. WILLIAM ROBERTS, JR. & ASSOCIATES 99 changes that histoplasmosis, tuberculosis, and 1 2 other infectious disease processes can cause 3 within the respiratory system and that 4 radiographically these disease processes can be 5 indistinguishable from the neoplastic disease." 6 I'd just like to expand upon that a 7 little bit. First, what are the other infectious 8 disease processes referred in that sentence? Can 9 you identify those? 10 Well, I could identify one. Α. 11 Q. Okay. 12 And that is the infection with the 13 organism called dirofilaria immitis. 14 And how is that contracted? Are you 15 going to spell it out for us all? That's a good 16 idea. 17 By mosquito. Α. 18 We'll give it to the court reporter. 19 Any other infectious disease 20 processes that you can think of here today that 21 would fall within that category?

```
22
                    Those are the ones that occur to me
23
       today.
24
              Q.
                    All right. And I'm going to refer to
25
       this one as DI, or is there a short term for this?
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
                    It's also called the dog heart worm.
                    All right. We'll go with dog heart
              Ο.
 3
       worm disease.
 4
                    Have you seen any data discussing
 5
       within the last ten years how many cases of dog
       heart worm disease in citizens of West Virginia
 6
 7
       there have been?
 8
                    I have none.
              Α.
 9
              Q.
                   Is that a reportable disease?
10
              Α.
                    I don't believe it is. Reportable,
11
       you mean reportable by law or Health Department
12
       regulation as an official communicable disease
13
       that must be reported to the Health Department, I
14
       assume?
15
                    Either/or. Either like the CDC has a
16
       list of reportable diseases, and then each state
17
       may have a list of reportable diseases; is that
18
       correct?
19
                    Small distinction. The CDC can't
20
       require that diseases be reported to it. To it,
21
       that's a state function, so each state has a list
       of reportable diseases. I'm not aware that this
22
       is a reportable disease in that sense.
23
24
              Ο.
                   In West Virginia?
25
              Α.
                    Yes.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      101
                    What about here in the great State of
 2.
       Tennessee?
 3
                    It is not.
              Α.
                    Okay. What are the symptoms of the
 4
              Ο.
 5
       dog heart worm disease?
 6
                  In humans?
              Α.
 7
                   In humans, yes.
 8
                  It presents as a pulmonary nodule.
 9
                   Is it associated with any other
              Q.
10
       symptoms?
11
                    Usually not.
12
              Q.
                    Okay. Histoplasmosis. I'm sorry, I
13
       should have done a little more research before
14
       today, but I didn't get around to it, so I don't
15
       know anything about histoplasmosis. Can you give
16
       me the five-minute lecture on the cause and the
17
       symptoms of that disease?
18
                  Sure. It's caused by a fungus.
19
       Histoplasmacapsulatum, which is resident in the
20
       soil in certain parts of the country, and West
21
       Virginia is within what's called the endemic area
22
       for histoplasmosis. It's transmitted to people
23
       who have close contact with the soil and sometimes
24
       even by the wind. The organism is inhaled and
25
       then can cause an acute infection, and it also has
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       some chronic cavitary infectious component to it,
       but the point that's here is that the body
       frequently contains the fungus, and within the
```

lung sets up an inflammatory reaction around the fungus, which over time coalesces and becomes harder and can present on chest X-ray as one or more pulmonary nodules.

- Q. Okay. How many cases of histoplasmosis have you personally been involved in?
- A. Oh, many, because Tennessee is also within the endemic area for histoplasmosis.
- Q. Is there a certain age group or section group that this disease attacks or is more likely to occur in?
- A. Well, the initial infection, which is often a trivial one, it may even be asymptomatic, can occur in children and young adults as they are out in the environment. It's not so much that the symptomatic cases are important here because even the asymptomatic cases, individuals, people have asymptomatic infections, can go on as the body contains this infection to later in life, sometime in their adulthood, present with chest X-rays that can have pulmonary nodules on them that will
 - A. WILLIAM ROBERTS, JR. & ASSOCIATES

present an element of confusion in interpretation or uncertainty in interpretation.

- Q. And I just want to make sure I have this right. It's a disease that children and young adults are most affected with, but which some individuals may carry with them until adulthood asymptomatically, but it would appear as a lesion on their lung?
 - A. That's, yeah, that's pretty close.
- Q. Okay.

- A. Those children and young adults don't all get disease -- disease implies symptoms -- but they may have an asymptomatic infection, and indeed the majority of them are asymptomatic or trivial, very mild.
- Q. Okay. But let's say a child, what are the symptoms, if I was symptomatic with histoplasmosis, what are those symptoms?
- A. Well, it could just be a prolonged upper respiratory infection or the symptoms can be determined very much by dose of exposure. We have, for example, it's well described in the literature to have individuals, whether children or young adults, who are susceptible suddenly exposed to a large dose of histoplasma in the
 - A. WILLIAM ROBERTS, JR. & ASSOCIATES

environment, they can get an acute pulmonary infection, which results in high fever, chills, striking pulmonary infiltrates, profound feeling of unwell that can last for, oh, a period of a few weeks.

- Q. And was that in an adult?
- A. It could be in a young adult, yes, or an older adult who is susceptible, right.
- 9 Q. But let's take the situation in a 10 younger adult, the upper -- he has the 11 histoplasmosis, the infection goes away, is my 12 understanding correct though that he still may

13 have something in his lung which later on in life 14 may appear as a nodule? 15 A. That's correct. 16 Okay. Even though he's not suffering 17 the effects of the infection? 18 Indeed, because he's not suffering the effects of the infection, what the body has 19 20 been able to do is contain the infection, and it 21 lays down fibrous tissue or granulomatous response 22 around it, and that very host response is what 23 creates the nodule that you can see on the chest 24 X-ray. 25 Is there any other type of screening Q. A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 tool, let's say a blood sample that would turn up the existence of the histoplasmosis in an 2. 3 individual that has this lesion on their lung? 4 A. The short answer is that the other 5 tests you could do, whether a blood test or a skin 6 test, would simply indicate prior exposure to the organism. That would be common. The question 7 would be, what's causing this spot on the lung? 8 9 It could be that, or it could be something else, particularly if the individual has other risk 10 11 factors apropos with the people whom you are 12 trying to screen here, i.e., they were long-term 13 smokers. 14 Just going back to the dog heart worm 15 disease in humans, again, is there an age group or 16 sex roup or racial group that that disease is more 17 likely to occur in? 18 Α. Well, that's also not a disease. In 19 humans --20 Q. I'm sorry. In humans, it's an asymptomatic 21 Α. infection. The worm is transmitted to the human, 22 23 if you will, speaking teleologically, the worm finds it's in the wrong host, shouldn't be there, 24 25 it gets stuck in the lung, and at that point a A. WILLIAM ROBERTS, JR. & ASSOCIATES 106 very similar enclosure phenomenon occurs. The 1 2 body walls it off. You get a foreign body 3 reaction, the worm dies, but you are left with the 4 scar, and the scar looks like a nodule when you 5 take a picture of it with an X-ray. 6 Because we do more X-rays on adults, 7 those are the ones in whom we find occasionally 8 nodules of unknown cause that sometimes lead to 9 further diagnostic studies. Are there other factors -- we talked 10 Q. 11 about smoking. Are there other factors that you 12 would go down in trying to rule in or rule out a 13 lesion being the heart worm or histoplasmosis or 14 tuberculosis? 15 A. For each of those, you would have some aspects of the medical history that would be 16 17 useful in somewhat increasing the odds in one way 18 or another, or at least in forming your decision, 19 I should say. For example, for the dog heart 20 worm, there are endemic areas in the country, and 21 there are areas where the dog heart worm is not a

```
22
       problem to the veterinarians and to pet owners.
23
       In those parts of the country, you don't have to
       worry about these lesions unless the person lived
24
25
       in an endemic area and then moved, and we have a
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      107
 1
       pretty mobile population.
                    West Virginia is within the endemic
       area of dog heart worm. It's in the endemic area
 3
 4
       for histoplasmosis, so that would not help you
 5
       distinguish what this nodule is, but you would
       know that the individual potentially could have
 6
 7
       been exposed to histo, and like the rest of the
 8
       country, there's tuberculosis in West Virginia and
 9
       more 20 years ago, according to this article in
10
       the West Virginia Medical Journal than now, so
11
       clearly a proportion of the population is going to
12
       be left with those scars.
13
                  Have you attempted to design within
              Ο.
14
       the parameters of what the plaintiffs in this case
15
       have put forth a screening program that could take
16
       into account some of the false negative problems
17
       that the infectious disease may cause in this
18
       screening program? Have you thought of ways that
19
       we could work around it or other procedures that
20
       could be implemented that could deal with that?
21
              Α.
                    No.
22
                    Because you go on to say -- well,
23
       I'm not sure it goes on, but you have not done
24
25
                    I have not done that.
              Α.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      108
                    Could you do that?
              Ο.
                    I would not do that.
 2.
              Α.
 3
                    Why would you not do that?
              Q.
 4
                    Because be mindful of the fact that I
              Α.
       am not expert here, and so I am very dependent on
 5
       experts in cancer treatment and cancer longevity,
 6
 7
       et cetera, but I don't think it's been shown that
 8
       the -- shown to the point that national groups,
 9
       expert advisory groups recommend such screening
10
       that earlier intervention will securely prolong
11
       life, improve the quality of life or improve
12
       survival, and absent that, one would be loath to
13
       enter into a screening program.
14
                  Does that have to do with the
15
       mortality rates of patients with lung cancers? Is
16
       that what we're talking about here, until science
17
       finds a better way to treat people more
18
       effectively with lung cancer, the program that the
19
       plaintiffs have proposed should not be started at
20
       all?
21
                    Well, that would be one of the end
22
       points. You would want to document some benefit
23
       to the individuals screened and those who are
24
       found to be truly positive.
25
                  Continuing on in your expert report,
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       "Dr. Schaffner is also expected to testify that
       the" -- I'm sorry -- "medical monitoring proposals
       of plaintiffs' experts do not comport with
```

```
generally accepted standards of medical practice."
 4
 5
                    The first question I have for you is,
       what proposals of plaintiffs' experts are you
 6
 7
       referring to in the first instance? What have you
 8
       reviewed to date?
 9
              Α.
                    I'm sorry?
                    I'm sorry. It was inartfully worded.
10
11
                    What plaintiffs' experts are you
12
       referring to in that statement? We've talked
13
       about Dr. Burns, and you have that in front of
14
15
                    Well, perhaps that should have been
16
       singular.
17
                    I just want to -- and that's one
       point I need to clarify here. Is the only Medical
18
       Monitoring Program that you have reviewed
19
20
       contained in the report of Dr. Burns?
21
             Α.
                   Yes.
22
                    MR. LATHAM: Object to the form of
23
       the question. Subject to that --
24
                    THE WITNESS: Yes, it is.
       BY MR. JEKEL:
25
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      110
 1
                    So we could change that statement to
       say, Dr. Schaffner is also expected to testify
       that the medical monitoring proposal of Dr. David
 3
       Burns contained in his revised report dated -- is
 4
       that February 3rd, 2000?
 5
 6
             A.
                 Correct.
 7
              Q.
                  Does not comport with generally
 8
       accepted standards of medical practice?
 9
                   MR. LATHAM: I'm going to object to
       the form of the question. Dr. Schaffner is not
10
       going to be limited by this report because Dr.
11
12
       Burns subsequently modified what he proposed in
13
       his deposition, and in addition, there are other
       experts in the case that have modified, so he's
14
15
       not going to be limited by this report in his
16
       opinions.
17
                    MR. JEKEL: I'd like to find out, you
18
       know, if he's going to expand or look at other
19
       reports, I want the opportunity to talk to him
20
       again about what proposals he has reviewed.
21
       BY MR. JEKEL:
22
                   Have you reviewed Dr. Burns'
             Q.
23
       deposition?
24
             Α.
                    I have not.
25
                   Do you expect to do that?
              Q.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
                   If Mr. O'Tuel and his colleagues ask
             Α.
 2
       me to do so, I would do so.
 3
             Q. Just as you sit here today, the only
 4
       medical monitoring proposal from the plaintiffs
 5
       that you have seen and are prepared to say
       generally does not comport with generally accepted
 6
 7
       standards of medical practice is the one contained
 8
       in the February 3rd, 2000 report of David Burns,
 9
       correct?
10
                    That's correct.
             Α.
11
                    Now, what generally accepted
              Q.
12
       standards of medical practice are you referring to
```

13 in that statement? 14 A. I was referring to the general 15 guidelines put forward by the Preventive Services, 16 United States Preventive Services Task Force and 17 other bodies concerning screening in populations. 18 Q. Were those documents included in this 19 stack of stuff you gave me today? 20 A. No. They're included in my general 21 medical background experience and other things 22 that I've encountered during the course of my 23 professional life. 24 If I were to ask you to prepare a 25 list of those documents that identified the A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 generally accepted standards of medical practice for which you refer to in this statement, could 2. 3 you provide me a written list? 4 I wasn't thinking of it principally 5 as this was drawn up as a specific list. It was 6 more a product of my general background and 7 expertise. 8 I'm trying to find out if there is a Q. 9 journal, text, monograph anywhere that you will be 10 relying upon for that statement that the Burns 11 report, as you sit here today, does not comport 12 with generally accepted standards of medical 13 practice. Well, as I sit here today, I can't 14 15 indicate a single document that I would consider 16 he "relied upon." 17 Q. Are there multiple documents that you 18 would rely upon? 19 Well, there are multiple documents 20 I'm sure that I have used, and I would more speak 21 to my general expertise and background. 22 And in the effort to save time, if I Ο. 23 were to ask you to provide me a list of those 2.4 documents, rather than ask you what one, what one, 25 could you produce me that list? A. WILLIAM ROBERTS, JR. & ASSOCIATES 113 Well, certainly not here today. 1 2 Q. No, no, no. 3 Α. And I'd have to consider it, because 4 I'm not thinking that I went through the medical 5 library or even my own files, et cetera, and 6 reviewed a list of -- a series of reports and 7 documents. I'm generally familiar with a number 8 of them. 9 Then let's go about it this way. Q. 10 What exactly did you do with this report to come 11 up with the statement that it does not comport 12 with generally accepted standards of medical 13 practice? What are the generally accepted 14 standards of medical practice that you were 15 referring to there? Can we make a list? 16 The screening, several of the 17 proposals for screening are outside those as it is 18 said in the next sentence that are endorsed or 19 recommended by any major medical groups, and so 20 the proposals, as they sit, are obviously novel, 21 they are different from, and therefore they are

```
22
       outside the accepted standards of medical
23
       practice, which do not require that kind of
24
       screening or endorse that kind of screening.
25
              Q. Because a major medical group does or
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
 1
       does not endorse a certain screening program, does
       that mean it's not generally accepted?
 3
                    And I guess the question is, does a
 4
       practice need to be endorsed by a medical group
 5
       before you will consider it generally accepted?
             A. I would think that by and large in
 6
 7
       this era, we would expect proposals, particularly
 8
       those that are comprehensive, extensive, and
 9
       expensive, to be the considered recommendations of
10
       expert medical groups evaluating data from a
11
       number of sources and making sure that they comply
12
       with the standards for screening programs that
13
       were previously discussed.
14
              Q.
                   Those were a lot of words. I'm not
15
       sure if I understood them all.
16
                    I want -- did you do anything, did
17
       you read his report on Medical Monitoring Program,
18
       what specifically did you do to say that program
19
       is not generally accepted? Did you say, is it
20
       endorsed by a medical group, major medical group?
21
       If not, it's not generally accepted, was that the
       extent of what you did to come up with those
22
23
       statements?
24
                    MR. LATHAM: Object to the form of
25
       the question.
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                    THE WITNESS: It clearly was not the
       only thing. It was not the extent of what I did.
 2.
       Part of what I did, as I said before, was
 3
 4
       reference that with my own general experience and
       background as well as my knowledge of what several
 5
       of these groups have stated in the past, and I was
 6
 7
       very aware that there were a number of groups that
 8
       had not endorsed this kind of screening program.
 9
       BY MR. JEKEL:
10
                   Do you know Dr. Merrill?
             Q.
11
                   Walter H. Merrill, surgical
12
       oncologist at the Vanderbilt University Medical
13
       Center?
14
                  I know a Walter Merrill who is a
             Α.
15
       cardiothoracic surgeon.
16
                  How about a Richard N. Pearson, III,
              Q.
17
       MD?
18
                  He may also be a member of our
              Α.
19
       surgical faculty.
20
              Q. John R. Roberts, MD?
21
              Α.
                  Likewise.
22
              Q. Dr. David Parbone?
23
                  He's a member of our medical oncology
              Α.
24
       faculty.
                   Kenneth R. Hande, MD?
25
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      116
 1
                   Ken Hande is also a member of our
              Α.
 2
       oncology faculty.
                   Pabs E. Check?
              Q.
```

I'm not familiar with that name. 5 How about Hak Choy, MD? Q. I'm also not familiar with that 6 7 Those are both radiation oncologists 8 9 here at Vanderbilt. Did you at all discuss with these individuals, who Vanderbilt University 10 11 advertises as those physicians who treat lung 12 cancer, the plaintiffs' proposal contained in Dr. 13 Burns' report? 14 Α. I did not. 15 Did you ask them whether they thought Q. 16 the screening mechanisms and those items were 17 generally accepted or whether that was something 18 they would endorse? 19 Α. I did not. 20 What medical groups, major medical Q. 21 groups, did you contact in an effort to determine 22 whether they have seen the program as proposed by 23 the plaintiffs and whether they have, in fact, 24 endorsed it? 25 Α. I did not contact any medical groups. A. WILLIAM ROBERTS, JR. & ASSOCIATES 117 1 What major medical groups are you referring to in there? The U.S. Preventive Services Task 3 Α. 4 Force. 5 All right. 6 Α. The National Cancer Institute, the 7 American Cancer Society. 8 Okay. Q. 9 And there are a number of others with which I am not quite as specifically familiar. 10 American College of Physicians, I believe, also. 11 12 And did you go to a document of these 13 groups or some statement that they may have put forth that you looked at to say, hey, you know, 14 15 they don't endorse this screening program? How 16 did you make the determination that the groups 17 that you identified did not endorse a program 18 similar to the plaintiffs'? I did that. You did that? You did? Do you have 19 Α. 20 21 these statements and item somewhere in your 22 office, possibly, or are they in here? 23 A. I think the NCI statement is there. 24 The others I think I got out of the library, but I 25 don't remember exactly. A. WILLIAM ROBERTS, JR. & ASSOCIATES 118 1 I don't think I have them in my office or at home. 2 3 Would it be something other than, I think you're right, the NCI statement was in 5 there. The other three, the Preventive Services, the American Cancer Society, and possibly the 6 7 American College of Physicians, is that something 8 you could give me a citation to that I could go 9 and look at their statement? 10 Well, my recollection is that I've 11 seen the American U.S. Preventive Service Task 12 Force report. I don't believe I have that in my

13 office, although it's possible. 14 Do you know what year that report 15 was? 16 I don't. Certainly not off the top of my head. 17 18 I looked at the latest at the time, and this has 19 happened within the last months. 20 Q. What about the others, the American 21 Cancer Society? 22 I can't give you a specific citation. 23 And when I saw them, I didn't Xerox them or anything. 24 25 Q. And the American College of A. WILLIAM ROBERTS, JR. & ASSOCIATES 119 1 Physicians? 2. Α. Likewise. 3 Likewise. Did you ask counsel for 4 Phillip Morris, or I'm sorry, counsel for RJR to 5 provide you copies of those materials? They provided the NCI, and I believe 6 7 I looked at the others myself. MR. LATHAM: That he is referring to. 8 9 MR. JEKEL: Very good. Appreciate 10 that. 11 BY MR. JEKEL: 12 I think we lost somebody. 13 Moving on in your report, he is 14 further expected to testify that the programs 15 proposed by plaintiffs' experts, again, to date, 16 that only includes Dr. Burns, correct? 17 A. Well, I think in discussions with 18 counsel, it was anticipated that there would be 19 more than one expert rather than limit, but --20 I'm just trying to find out what you 21 have discussed or who you have discussed in 22 addition to Dr. Burns today so I can ask you about it, and if it's limited to Dr. Burns today, that's 23 fine. If it's not, let me know. 24 25 I believe we've only discussed Dr. A. WILLIAM ROBERTS, JR. & ASSOCIATES 120 1 Burns to date. 2 Thank you. 3 "He is further expected to testify 4 that the programs proposed by plaintiffs' experts may put the citizens of West Virginia in serious 5 6 risk of harm due to false negatives and false 7 positives." 8 Now, does that statement, "The 9 citizens of West Virginia," is that the entire 10 population of West Virginia or that subset group 11 of the population that would fall under 12 plaintiffs' program? 13 Α. The latter. 14 The latter. Q. 15 Principally. Α. So citizens of West Virginia could be 16 17 limited to those citizens of West Virginia that 18 fall within the plaintiffs' definition of getting 19 medical monitoring? 20 And those members of families, 21 relations and friends, who in the course of

22 medical monitoring and the subsequent treatment, 23 because adverse effects occurred to the person who was monitored would also suffer grief and concern 24 25 and et cetera. A. WILLIAM ROBERTS, JR. & ASSOCIATES Basically, someone thinking that they 1 have cancer when really, in effect, all they have is the dog heart worm, correct? Is that what you 3 4 are referring to there? 5 A. Like that. 6 What other harm -- what other 7 serious risk of harm are you identifying as it 8 relates to false negatives and false positives? A. Well, the false positive issue is one 9 10 where people can be inappropriately identified in 11 the initial screening process as having a lesion 12 consistent with a neoplasm that then requires them 13 with this new knowledge to have a further work-up, 14 and that the work-up might well include an 15 invasive procedure, and the invasive procedure may 16 be associated with adverse events. 17 What are the invasive procedures that Q. 18 you are contemplating? 19 Well, if a lesion consistent with, Α. 20 but not yet diagnostic of a cancer is determined, one might, as we discussed previously, undergo 21 bronchoscopy, skinny needle aspiration, one might 22 23 even be subjected to a thoracotomy in order to get 24 tissue, and all of those procedures have hazards 25 associated with them. A. WILLIAM ROBERTS, JR. & ASSOCIATES 122 I'm just -- what type of hazard do you require before it raises to the level of 2 serious risk of harm? Is there any mathematical 3 4 quotient that goes along with that? Is serious your word? Did you put that in there? 5 Serious is a word that I'm content 6 7 with because I think the issues are the ones that 8 relate to serious adverse effects. Everything 9 from potential anesthesia-related deaths to a 10 pneumothorax that might occur or a complicating 11 infection in any of these more invasive diagnostic 12 procedures. 13 I just want to make sure that that Q. 14 sentence that we're talking about, the serious 15 risk of harm that you are referring to is the 16 invasive procedures that we've identified in 17 addition to the general problems of a person maybe 18 believing that they do or do not have cancer when 19 the opposite is true? 20 Α. Yes. 21 So are those all of the serious risks 22 of harm that you are dealing with here, is that 23 the universe? 24 MR. LATHAM: Again, are you talking 25 about false positives here? A. WILLIAM ROBERTS, JR. & ASSOCIATES 123 1 MR. JEKEL: False positives or false 2 negatives. THE WITNESS: Well, the issue's

related to -- generically speaking, I think that 5 is correct. You could also have concerns related to false negatives, people perhaps being 6 7 complacent when they might be more concerned about the tumor that is really there, but the test 8 9 reveals as negative. This is not a sentence that addresses the issue of even among the true 10 11 positives what's the benefit. 12 BY MR. JEKEL: 13 Q. That's the next statement, is it not, 14 in your report? 15 Not exactly, because it doesn't 16 address the issue of harm, but it could be 17 encompassed within that. 18 Q. Okay. Now, the last statement there, 19 "Additionally, screening asymptomatic patients for 20 lung cancer has not been shown to reduce mortality 21 or morbidity, a prerequisite for an acceptable 22 monitoring program." 23 My first question is, what is your 24 current knowledge of what the mortality rate is 25 for a person with lung cancer? And it may depend A. WILLIAM ROBERTS, JR. & ASSOCIATES 124 1 on what stage that cancer is, and we can break it 2 down, if that's necessary. MR. LATHAM: Object to the form of 3 4 the question. 5 THE WITNESS: It's outside of my area 6 of expertise, and I rely here on the statements 7 from authoritative bodies such as the National 8 Cancer Institute that indicate that to date there 9 has not been a therapeutic program that impacts favorably the mortality of people who have lung 10 11 cancer. 12 BY MR. JEKEL: Fair enough. What statements are you 13 Q. relying on, and it may be, there may be a whole 14 15 host of them. Again, I just want to make sure I 16 have the universe of the materials you will rely 17 on for the statement that you need to reduce 18 mortality and morbidity for something to be an 19 acceptable monitoring program. 20 A. I think that that goes back to the 21 indications for design for and standards for 22 screening programs that we would find in texts of 23 clinical epidemiology such as I have indicated 24 before. In other words, unless there is a 25 benefit, why screen? And unless you can reliably A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 assure people that there will be a benefit, it's 2 an intrusive thing to do. 3 The first admonition of the 4 Hippocratic oath is, don't do any harm, and so you 5 would want to make sure that you're not doing any 6 harm. 7 I understand. However, your 8 expertise is not in, let's say, hypothetically 9 speaking, that through the program that plaintiffs 10 have designed, we could detect 50 more cancers in 11 a Stage 1 state, lung cancers through this 12 process, and that 80 percent of Stage 1 cancers

13 could be treatable, would treating the 80 percent 14 of that number be a benefit? 15 Only if it resulted in decreased Α. 16 morbidity and increased longevity and an increased 17 quality of life, and my understanding is that that 18 goal has not yet been demonstrated. 19 Okay. I know earlier we talked about 20 the diseases that you opined or that you would 21 agree cigarette smoking can cause. Were there --22 and again, I'm referring to Dr. Burns' report, 23 paragraph 7. Are there diseases, other than those 24 listed in paragraph 7 of Dr. Burns' report that 25 you believe as a medical doctor cigarette smoking A. WILLIAM ROBERTS, JR. & ASSOCIATES 126 1 causes? 2 I don't believe so. I can't think of Α. 3 any, at least off the top of my head, but I'm not 4 here representing myself as an expert on the 5 relationship of cigarette smoking and consequent 6 disease. 7 What about on the treatment of lung Q. 8 cancers, Stage 1 versus Stage 2? 9 Certainly not. Α. 10 Q. That may eliminate some of these 11 questions. 12 Doctor, do you have an opinion as to 13 whether a person who has a history of smoking 14 cigarettes is at a significant increased risk of 15 contracting serious latent disease above a person 16 who does not have a history of smoking cigarettes? 17 A. I'm not sure -- I don't know what you 18 mean by latent disease. 19 Something that may take a period of Ο. 20 time to discover. I smoked for five years, smoked 21 for ten years, that the last day of that tenth 22 year I looked good on my lungs. Five years later 23 I have some spots on my lungs. That's what I am 24 referring to as latent, may take a while to 25 develop after the process or the activity stops, A. WILLIAM ROBERTS, JR. & ASSOCIATES 127 1 smoking. 2 In light of that helpful explanation, 3 could you rephrase the question? 4 I'm not sure I can. Q. 5 Do you have an opinion, Doctor, if a 6 person who has a history of smoking cigarettes is 7 at a significantly increased risk of contracting a 8 disease that may not be discovered for some time 9 after that person may stop smoking, as opposed to 10 a person who has never smoked? 11 I must admit, I'm still a little Α. 12 confused by the question, and the issue aside of 13 dose and duration of cigarette smoking, let's just 14 deal with it in a vague, general way. I think 15 you're asking me whether I agree that someone who 16 has smoked some dose and duration of cigarettes 17 sufficient to put them at risk, disease X, can 18 discontinue smoking, be at that point free of 19 disease X, but develop disease X years later. 20 Q. A. 21 If that's your question, my general

```
22
       knowledge is, it depends on the disease, but
23
       clearly the answer is yes.
              Q. Now, on the question of dose
24
25
       duration, is that an area, as it relates to
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      128
 1
       cigarette smoking and disease that you feel you
       have expertise in?
 3
                    I explicitly do not.
              Α.
 4
              Q.
                   All right. So you cannot tell me how
 5
       many cigarettes a day for how long a period of
       time a person must smoke before they are at an
 6
 7
       increased risk or at which no risk of developing
 8
       lung cancer exists?
 9
              Α.
                   Correct.
                  Okay. Do you have any expertise as
10
              Q.
11
       it relates to the incidence of lung cancer and at
12
       what age or sex that begins to climb?
13
                  I do not.
              Α.
14
                   Dr. Schaffner, does any of your --
15
       would your expertise allow you to separate out
16
       from smoking and other environmental factors the
17
       incidence of lung cancer and when it begins to
18
       climb?
19
              Α.
                    It does not.
20
                  All right. Do you have an opinion as
       to whether cigarette smoking is addictive?
21
                   I do not.
22
                  Do you have an opinion as to whether
23
              Q.
24
       nicotine is addictive?
25
              A.
                   I do not.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      129
                    Have you ever been a smoker?
 1
              Ο.
 2.
              Α.
                    Yes.
 3
                    For how long and of how many packs?
              Q.
                   No packs. I smoked a pipe for about
 4
              Α.
       20 years, usually in the evenings, and an
 5
 6
       occasional cigar.
 7
                   And you don't smoke the cigar
 8
       anymore?
 9
                   I don't smoke the cigar anymore or
              Α.
10
       the pipe.
11
                  When you're evaluating and treating
       patients, what other risk factors in that
12
13
       particular patient do you consider?
14
                    I guess, to put it the other way,
15
       when you are evaluating a patient, do you look at
16
       other risk factors that patient may have? The
       patient presents with an infectious disease,
17
18
       patient has a history of cigarette smoking, is
19
       that something you'll take into account?
20
                    MR. LATHAM: Object to the form of
21
       the question.
22
                    THE WITNESS: Well, you try to take a
23
       comprehensive medical history, and you ascertain
24
       as much information as you can about the patient.
25
       When you are a generalist, this is very elaborate.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      130
 1
       When you are performing infectious diseases
 2
       consultation, it can be very focused, and so it
       depends on the circumstance, if we're working with
```

a trauma surgeon who has got an acute abdominal 5 problem, the larger medical history of the patient is of less immediate moment than in other 6 7 circumstances, but generically speaking, you would like to know as much about the patient as possible 8 9 in order to help you care for the patient 10 appropriately. 11 BY MR. JEKEL: 12 The patient presents to you with Q. 13 abdominal infection, the patient also presents 14 with a serious history of cigarette smoking and 15 maybe some other symptoms, just general shortness 16 of breath, when you are developing a plan or 17 treatment for that particular patient, do you 18 consider that smoking history in the treatment you 19 will give a patient? 20 A. You may. You might well. 21 If this was the first time that 22 patient had been to the Vanderbilt facility here, 23 would you order a chest X-ray on that patient? 24 Now, you are speaking to me in my 25 context as an infectious diseases consultant? A. WILLIAM ROBERTS, JR. & ASSOCIATES 131 1 Q. Yes. 2 And so the primary care physician would already have made a determination about 3 whether for that physician's reasons a chest X-ray 4 5 would be appropriate. If we see the patient for 6 the abdominal infection, that I believe you 7 suggested, and the patient has symptoms that are 8 also referable to the chest, a cough or something 9 abdominal on physical examination, and there was not a recent chest X-ray, certainly in that 10 context we would suggest that a chest X-ray be 11 12 performed. 13 Can I assume that you have not Q. reviewed any of Christa Blankenship's or Maya 14 15 Sebo's medical records? 16 You may so assume. 17 So as you sit here today, you cannot 18 tell me whether Ms. Blankenship and Sebo are at an increased risk of developing lung cancer? 19 20 Α. I cannot. 21 Q. I did note in the copy of the Third 22 Amended Complaint that is in your stack, 23 throughout there is some handwriting that appears 24 in the margins, and maybe I can find some, I just 25 wanted to find out, is that your handwriting? A. WILLIAM ROBERTS, JR. & ASSOCIATES 132 1 That's not my handwriting. Α. 2 Do you know whose handwriting it is? Q. 3 I don't. 4 Q. Do you attach any significance to the 5 handwriting that appears in that document? 6 No. Α. 7 Again, the copy of this document, was that provided to you for counsel for RJR? 8 9 Yes, it was. Α. 10 Have you asked them whether this was Q. 11 their handwriting? 12 I didn't pay any attention to the

13 handwriting. 14 Q. Okay. Doctor, are you aware that in 15 this case the Court will actually determine the 16 extent of the -- or the parameters of any Medical 17 Monitoring Program put into place? 18 That's come up in the discussions. I think that's been suggested to me. That's what's 19 20 being asked of the Court, as I understand it, by 21 the plaintiffs. 22 Q. Do you think that's reasonable? 23 Unreasonable? MR. LATHAM: Object to the form of 24 25 the question. Calls for legal conclusion. A. WILLIAM ROBERTS, JR. & ASSOCIATES 133 1 THE WITNESS: With respect to the 2. Court, I think it is preferable that expert 3 medical advisory committees appropriately constituted look at good, solid data from a number 5 of sources and provide the kind of advice and 6 guidance that such expert advisory groups do to 7 all aspects of medical practice, and yes, if asked, I think that's a preferable way to go than 8 9 to ask a Court to do that. 10 BY MR. JEKEL: 11 Q. Earlier I talked about the screening 12 programs that you have been involved in. Have any 13 of those risen to a level of what you would call 14 medical monitoring? 15 A. Oh, now you will have to define for 16 me the distinction, because I asked that before, 17 and you wanted me to include screening. 18 Q. Screening may just be one part of it. 19 I'm getting more to the treatment aspect of it, 20 and do you have in your mind a definition of 21 medical monitoring that you used when you reviewed 22 these materials? 23 Α. My notion was that these materials 2.4 rather defined medical monitoring for me, that 25 they were a screening program, a proposed A. WILLIAM ROBERTS, JR. & ASSOCIATES 134 screening program that had treatment, obvious 1 treatment implications, even though the specific 2 3 treatment was not specified. I thought that was a 4 reasonable assumption, else why screen to find 5 people who are positive? 6 The answer to your question is that 7 all of the screening programs that I have been 8 involved in had defined results about what 9 implications for what one did with positive 10 results, individuals who are found to be positive. 11 Sometimes in the context of the Infection Control 12 Program, it might just mean instituting the 13 appropriate infection isolation precautions. 14 Earlier we talked about, I think this 15 was one of the materials you referred to, the U.S. 16 Preventive Service Task Force report. Is that, in 17 fact, the document? 18 A. Well, this is kind of my memory of 19 the document. Actually, this looks like maybe a 20 larger version than the one I saw. 21 Q. I may have some.

```
22
                    But I can't -- yeah, it looks
23
       similar.
24
              Q.
                    And this was a document that you were
25
       relying on?
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       135
 1
                    I think so.
                    Yeah.
 2
 3
                    Well, if you're not, now is the time
              Ο.
 4
       to say it.
 5
                    Well, I didn't -- that looks like a
              Α.
       copy of the document, I think. I can't remember
 6
 7
       if that's the same size or whether it's been
       enlarged a little bit. My memory is a little
 8
 9
       murky about that.
10
                   I just have a small excerpt here, and
              Q.
11
       I want to direct you to a certain --
12
                   I do think mine was a smaller. It's
13
       not the 8-and-a-half by 11 format. I think the
14
       book I held in my hand was somewhat smaller than
15
       that.
                    Part 2 under Mythology.
16
              Q.
17
              Α.
                    Mythology?
18
                    Methodology, I'm sorry. It's been a
              Q.
19
       long day for me, too. You don't know what time I
20
       had to get up to be here this morning.
21
                    You're nice to tolerate my teasing.
              Α.
22
                    You're nice to tolerate my questions.
              Q.
23
              Α.
                    I'm sorry.
24
                    I just want to make sure that this is
              Q.
25
       part of a document that you relied upon, and if
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       136
       you will indulge me, I'm going to ask you if you
       agree with the statement that I have highlighted
 2.
 3
       there.
 4
                    "The second criterion for selecting
 5
       preventative" --
 6
             Α.
                    Excuse me for a moment. May I just
 7
       take a moment?
 8
                  Go right ahead.
              Ο.
 9
                    I think I'm ready.
                    Doctor, referring to the highlighted
10
11
       paragraph in the section on Methodology, the
       authors note, do they not, that "The second
12
13
       criterion for selecting preventative services for
14
       review was that the maneuver had to be performed
15
       in the clinical setting. Only those preventive
16
       services that would be carried out by clinicians
17
       in the context of routine healthcare were
18
       examined. Findings should not be extrapolated to
19
       preventive interventions performed in other
20
       settings. Screen tests are evaluated in terms of
21
       their effectiveness when performed during the
22
       clinical encounter, i.e. (case finding) screening
23
       tests performed solely at schools, work sites,
24
       health fairs, and other community locations are
25
       generally outside the scope of this report.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                       137
 1
       preventive interventions implemented outside the
       clinical setting (e.g., health and safety
       legislation, mandatory screening, community health
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promotion) are not specifically evaluated, 4 5 although clinicians can play an important role in promoting such programs and encouraging the 6 7 participation of their patients. References to those types of interventions are made occasionally 8 9 in sections of this book." 10 Did I read that correctly? 11 You did. Α. 12 The first sentence in there, that the Ο. 13 screening had to be performed by clinicians in the 14 clinical setting, is it your understanding that 15 the program proposed by the plaintiffs includes 16 screening that would happen in a clinical setting? 17 I don't think it's specified that it 18 need be performed in a clinical setting. 19 And do you have, based on what the Q. 20 authors in this book concluded, an opinion as to 21 whether it should or should not be performed in 22 that setting? 23 I have the opinion that the sentence 24 beginning "Findings should not be extrapolated to 25 preventive interventions performed in other A. WILLIAM ROBERTS, JR. & ASSOCIATES 138 1 settings" could have been further elaborated by the authors because I think this is their intention such that the sentence would read: 3 Findings should not be extrapolated to preventive 4 5 interventions performed in other settings because 6 in those settings the screening tests are likely 7 to be less effective. 8 But the conclusions of the authors in Q. 9 this report were limited to only those screenings performed in the clinical setting? 10 Surely, but the important notation is 11 12 that if you are thinking of performing screening 13 in a larger, less selected population than the 14 population that occurs among self-selected 15 individuals who present themselves to the 16 physician, that is, the clinical setting, there 17 the -- in the larger, less selected population, 18 the results are going to be even more problematic 19 for any screening test than in the clinical setting. The ratio of false positives to true 20 positives will be larger in the less selected 21 22 population. 23 Knowing what you know about Dr. 24 Burns' proposed plan, are there aspects of his 25 plan that could be done outside of a clinical A. WILLIAM ROBERTS, JR. & ASSOCIATES 139 1 setting? 2 Addressing the plan that is the plan Α. 3 that I have seen, the one that's called the Revised Report, the limitation on where the 5 various tests could be performed is entirely a 6

- pragmatic one. It relates to physical facilities, and the sufficiency of creating an appropriate environment where that can be done appropriately, and that the tests can be interpreted skillfully.
- 10 Earlier, and I believe you were 11 discussing the plaintiff's proposed plan at this 12 time, you said that the -- and I'm hoping I'm

7

8

9

13 paraphrasing correctly, the plaintiffs' plan was 14 comprehensive, extensive, and expensive. Does 15 that ring a bell at all? 16 Sounds like something I might have 17 said. It's been a long time, and it is all those 18 things. 19 What cost information have you 20 reviewed for purposes of the plan that's enclosed in Dr. Burns' report? Have you reviewed anything 21 22 specifically? 23 Α. No. I haven't. 24 If it was cheaper to perform some of Q. 25 these aspects outside of a clinical setting, how A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 would that factor into your opinion on the plan? Would you give up the expense for the less or the 2. 3 more likely to have false positives or false negatives outside of the clinical setting just to 4 5 make it least expensive? Do you follow what I'm 6 saying? 7 Your question took an unexpected turn Α. 8 right at the end. 9 Let me rephrase it. 10 If it would make the plan, overall 11 cost plan of the plaintiffs' program less 12 expensive to perform some of the services or some 13 of the screening tasks that are promulgated in 14 here outside of the clinical setting, would you be 15 in favor of that solely to bring the cost of the 16 plan down knowing that doing that would increase 17 the likelihood of the inherent problems you had 18 doing screening outside of a clinical context? 19 Yeah, I'm afraid I have been 20 misunderstood. 21 The inefficiencies, we might call 22 them that, of performing a screening program, any 23 screening program at all in a less selected 24 population relates not to the physical environment 25 in which the test is performed, but rather that A. WILLIAM ROBERTS, JR. & ASSOCIATES 141 the test, which has certain sensitivities and 1 2 specificities is now being applied to a 3 population, as an unselected population, in which 4 the true occurrence of disease is lower, and when 5 that happens, the performance characteristics of 6 the test are affected adversely. The less you 7 select the population that you are applying the 8 test to, the higher the ratio of false positives 9 to true positives, you get more noise than you get 10 action, and then you have to deal with all the 11 noise. 12 As to the question of expense, which 13 is not a question I have addressed in any expert 14 fashion, clearly a characteristic of any screening 15 program is to do it in as efficient and cost 16 effective fashion as possible, but that even 17 though you make the testing more cost effective 18 does not mean that the results get any better. 19 No, I think we were -- do you see a 20 lot of patients with breast cancer here at 21 Vanderbilt?

22 Even in my consultative practice, 23 that disease does not occur very often, so there again I think you meant when you said you, you 24 25 mean me personally. A. WILLIAM ROBERTS, JR. & ASSOCIATES 142 1 You personally, yes. Yeah, we have a big breast cancer Α. 3 diagnosis treatment center here, but that turns 4 out not to be a source of many infectious disease consultations, which means that they are doing 5 6 things right. 7 Do you know what criteria for Q. screening of breast cancer they use here at 8 9 Vanderbilt? 10 Α. I don't. 11 Do you know what the generally Q. 12 accepted principles by the major medical 13 associations are for screening of breast cancer in 14 the United States? 15 A. I don't. I'm not expert in that 16 area. Q. Okay. Do you have an opinion as to 17 18 whether women over 40 years or 50 years old should 19 be evaluated by their physicians prior to having a 20 mammogram performed? 21 I have no opinion on that. 22 MR. LATHAM: Object to the form of 23 the question. Go ahead. 24 THE WITNESS: I haven't got any 25 opinion on that. A. WILLIAM ROBERTS, JR. & ASSOCIATES 143 BY MR. JEKEL: All right. I know you've done some 2. Q. work with tuberculosis, so I'm hoping you'll have 3 some information on this. What about current 4 screening parameters for tuberculosis among school 5 teachers? Are you familiar with any of that? 6 7 A. I know there's been some recent 8 discussion about that. 9 Q. And what has the recent discussion 10 centered around? A. Well, the principal issue, as I 11 12 understand it, has been the traditional one of 13 identifying teachers such that they will not 14 transmit tuberculosis to pupils and to colleagues 15 at work. Would the same be true of healthcare 16 Q. 17 professionals? 18 A. The notions are entirely similar 19 except in the healthcare professional, we have a 20 dual concern, which is because they are at 21 increased risk of acquiring tuberculosis, we have 22 a TB control program that is designed to also 23 detect early disease in them, disease that they 24 may have acquired, if you will, on the job. 25 And do you have an opinion whether a A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 school teacher or healthcare professional should be examined by their physician prior to having them undergo the screening process for TB?

No. I don't have an opinion about Α. 5 that. I'm not familiar with the various proposals or current procedures in those areas in different 6 7 school districts. Q. What are the current screening 8 9 techniques for TB? 10 A. They have profound limitations. One 11 would be the -- one that's widely used obviously is the tuberculin skin test. That detects past 12 13 exposure to the organism that causes TB, but 14 doesn't say anything about the current disease 15 status, so those who have a positive skin test, if 16 what you are interested in is determining what 17 their current disease status is require a clinical 18 evaluation that includes a chest X-ray. 19 And which of the screen mechanisms do Q. 20 you find as it relates to TB most likely to give 21 you a true result? 22 MR. LATHAM: Object to the form of 23 the question. 24 THE WITNESS: Yeah, I'm not entirely 25 sure what you mean by "a true result." A. WILLIAM ROBERTS, JR. & ASSOCIATES 145 BY MR. JEKEL: 1 2 If we're looking for whether the person is currently suffering from TB or currently 3 can be a carrier, expose other people in a 4 5 hospital, is there one screening mechanism that 6 you believe is more likely to give you that 7 information? 8 A. Permit me to answer the question this 9 way. It's frequently -- it is most commonly a two-step process in which you would first use 10 tuberculin skin testing, and to define a group 11 that has a positive test, it then would be 12 13 examined and given a chest X-ray. On rare, in certain defined circumstances, where that process 14 15 was thought not to be appropriate to the 16 population, for example, in large prison systems, 17 some prison systems have gone to rapid, small 18 format chest X-ray screening. 19 Q. And to do those two steps -- I'm a school teacher. I just get hired into the school 20 21 district. They want to do these two tests on me. 22 Do you think it's appropriate for the school 23 district to do those tests, or is me as the new 24 teacher, should I go to my physician and have him 25 recommend that, yeah, you should have the test A. WILLIAM ROBERTS, JR. & ASSOCIATES 146 done before those are performed? 1 2 A. Well, I don't know if I have an 3 opinion on this. In the former example, it would be a condition for employment. 5 You don't have a choice? Q. 6 There isn't any choice involved, is 7 there? 8 Do you know if they screen for TB Q. 9 among the faculty and staff at Vanderbilt 10 University? 11 Yeah, we have a tuberculosis 12 screening control program that includes for those

13 of us with patient care tuberculin skin test. 14 Q. And do you give the individual the 15 option of getting an opinion from their physician 16 before they undergo the skin test, or is it a 17 condition of their employment? 18 That's a condition of their 19 continuing to work and to have privileges here. 20 And have you ever had a situation 21 where there's been a false positive? 22 A. Sure. 23 Did you think that false positive 24 inflicted serious risk of harm to that individual? 25 A. The false positive test, the test A. WILLIAM ROBERTS, JR. & ASSOCIATES 147 1 that subsequently was found to be false positive or that we thought was a false positive test 2. usually does not in and of itself inflict anything 3 more than a period of concern and consternation on 5 the part of the individual and perhaps some on the 6 part of the institution because we would be 7 concerned that they might have acquired the infection on the job, but this is quite different 8 9 than starting with some roentgenographic screening 10 process where you identify things that look like 11 pulmonary nodules. That's a very different kind 12 of --13 Now, earlier we talked about -- I'm 14 going to refer to your expert report again, and 15 reviewing specifically the plaintiffs' proposed 16 Medical Monitoring Program, and I wanted to ask 17 you whether you used any kind of decision making 18 model in coming up with the statements about it 19 not being generally accepted and it causing 20 serious harm. Did you follow a decision making 21 model, a decision tree, if you will? 22 Α. I did not. 23 You did not? Ο. 24 MR. LATHAM: Just for the record, 25 he's referring to the expert disclosure, Exhibit A. WILLIAM ROBERTS, JR. & ASSOCIATES 148 1 1. 2 MR. JEKEL: I'm sorry. Yes. 3 MR. LATHAM: That's fine. 4 BY MR. JEKEL: 5 I'm just going to hand you a portion 6 of a document by Dr. Eddy. It's called "Common 7 Screening Tests," and before we go through it, 8 I'll ask you a couple of simple questions. Have 9 you ever seen that document before? I have not seen this document. 10 Α. 11 As you sit here today, are you in a Q. 12 position to agree or disagree with statements 13 contained therein? 14 Surely not. Α. 15 My familiarity, my general 16 familiarity with Dr. Eddy notwithstanding. 17 Q. Do you know Dr. Eddy? 18 I don't personally, but he's -- it's Α. 19 a name that's familiar to me. 20 And is it familiar in the field of 21 designing a screening test similar to what we have

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22
       been talking about here this afternoon?
23
            A. Well, this is an area in which Dr.
24
      Eddy at least used to write fairly extensively,
25
       and he was considered an authority. I think he's
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
1
      kind of semi-retired now.
             Q. But you don't have any opinion as to
      whether this text is still authoritative as it
 3
 4
       relates to screening?
             A. I haven't seen this text.
 5
                  Would you agree that evidence
 6
             Q.
 7
      directly connecting the application of a screening
8
      test with the occurrence of a health outcome would
9
      be rare?
                 I'm sorry.
It's my shorthand. Talking about
10
             Α.
11
             Q.
12
       connecting a screening test with a health outcome,
13
       chest X-ray, lung cancer, do you follow me there?
14
             A. I --
15
                  Screening?
             Q.
                  I wouldn't usually define the
16
17
       detection of lung cancer as the health outcome;
18
       that's the detection of the disease.
19
             Q. Okay.
20
                  The health outcome would be improved
             Α.
21
       survival, reduced mortality.
                 Very well. That's fine, too.
22
             Q.
23
                   Do you think, using those two
24
       examples, the extending the benefit, the life, do
25
       you think that it's rare that you find the
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                     150
       screening directly linked to the outcome?
             A. Certainly not in infectious diseases
 2.
 3
       in the ones that I have been involved with.
 4
             Q. In what cases have you seen direct
       correlation with the screening mechanism and the
 5
       outcome or the benefit?
 6
7
             A. Well, as I said, we've defined the
8
      outcomes that we desired in a very specific way so
9
      that when we instituted the screening program, for
       example, we were able to define those people in
10
       the intensive care unit that were colonized with
11
12
      that resistant bacteria, we were able then as a
13
      consequence to isolate those patients more
14
       securely, and in due course we saw a reduction in
15
      that intensive care unit of the occurrence of
      transmission of that bacteria. That was the
16
17
       result. It's very tight.
18
             Q. Right. But doesn't that also suffer
19
      the same problem that you talked about with the
20
      Lancet study, that it's only a very local
21
      population?
22
                  Surely. But the principles of
23
      working in an intensive care unit in that kind of
24
       circumstance have been demonstrated repeatedly by
       a number of different investigators in a number of
25
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
1
      different settings so that the CDC and other
       expert advisory groups suggest that as a method
       that's tried and true, it has stood the test of
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experience in a number of different settings, it's been confirmed, and you may well try that in your own setting with the expectation of success.

- Q. When you design these screening programs, were you looking at comparing the test benefits, harms, and costs?
 - A. Always.

- Q. Is that an element of every -- in any type of screening program that you've got, before you implement a screening program, you've got to look at the benefits, the harms, and the costs?
- A. In a summary way, you would like to look at the benefits, potential benefits, potential harms, and the costs that are going to be accrued, that's correct.
- Q. And who makes that determination as to whether -- I mean, wouldn't you agree that it should be the patient who makes that call as to whether the test benefits, harms, and costs really make a difference?
- A. I think the patient and their physician, obviously, discuss all aspects of their
 - A. WILLIAM ROBERTS, JR. & ASSOCIATES

care, and I do so in the context of individual patient care, but the question of whether to institute a screening program as opposed to the case finding that you were talking about in the Preventive Services Task Force, this in large program, in large populations, I think that that transcends the issues of individual doctor/patient relationships, and that's exactly where you need expert advisory groups evaluating the best possible data providing guidelines about how to proceed or whether or not to proceed at all.

- Q. In evaluating the plaintiffs' proposed program, did you endeavor to talk to lung cancer patients and physicians who treat those lung cancer patients to determine what their opinions on that subject were?
 - A. No. I did not.
- Q. Can you, given the information you have on the number of tuberculosis cases in West Virginia and the endemic histoplasmosis and dog heart worm disease, can you come up with a formula to tell me exactly how many false positives or false negatives the plaintiffs' proposed monitoring program will turn up?
 - A. I cannot.
 - A. WILLIAM ROBERTS, JR. & ASSOCIATES

- Q. Do you know of anybody who can do that based on -- there's obviously data on the instances of histoplasmosis in West Virginia, right?
- A. It would be a very difficult task, and there are people who are skilled in such medical monitoring, but you can't solve the medical model if you don't have certain critical data, and the proportion of individuals of whatever age and background in West Virginia that have lung nodules identified by the various screening modalities is, I believe, currently

13 unknown, and I think it would be difficult to 14 extrapolate from other data to that specific 15 population. 16 What information do you have Q. 17 specifically about the group of people in West 18 Virginia that may fall under this program and what their background would be? Do you know how many 19 20 people we're talking about? 21 Α. There may have been estimates in Dr. 22 Burns' deposition, but excuse me, report, revised 23 report. It is late in the day. 24 But the aspect that I bring to this 25 discussion is that I know that West Virginia is in A. WILLIAM ROBERTS, JR. & ASSOCIATES 154 1 the endemic area for histoplasmosis and for the dog heart worm and has had in the past high rates 2. 3 of tuberculosis, so that one can expect some false 4 positives, the extent to which remains unknown, 5 but it will be final. It will be real. 6 Of those three -- histoplasmosis, Q. 7 tuberculosis, and the dog heart worm -- are there 8 generally trends as it relates to West Virginia, 9 whether the incidence of that infection is 10 increasing, decreasing, remaining constant? 11 Some slight data, but recall that 12 these are all infections that can be acquired very 13 frequently without symptoms and then kind of like 14 a long fuse, only present as a pulmonary nodule 15 many years later. Having said that, I believe 16 there are no data on the dog heart worm or 17 histoplasmosis, but new infections, new clinical 18 infections with tuberculosis seem to be declining 19 in West Virginia in concert with their 20 tuberculosis control program. 21 Is that --Q. Remember, it's the infections, 22 Α. 23 however, that occurred 20 and 30 years ago that we 24 are going to run into trouble with today, so it's 25 noteworthy and to be applauded that there are new A. WILLIAM ROBERTS, JR. & ASSOCIATES cases of tuberculosis are falling, but they will 1 2 have a lesser impact on this particular issue. 3 Q. I understand. As an admitting 4 physician at Vanderbilt, are there any 5 circumstances under which you would recommend a 6 chest X-ray to an asymptomatic smoker? 7 MR. LATHAM: Object to the form. 8 Asymptomatic for lung cancer? 9 MR. JEKEL: Yes. 10 THE WITNESS: I was about to say that 11 you don't get admitted to Vanderbilt if you are 12 asymptomatic unless you are a candidate for 13 surgery, and then, even then today if you are 14 asymptomatic, it is no longer routine to do a 15 chest X-ray, so there would have to be another specific indication, and, of course, I don't admit 16 17 those patients, so if the you was directed at 18 me --19 BY MR. JEKEL: 20 Q. I was talking about you as an 21 admitting physician in your capacity as a doctor

22 of infectious disease when you have admitting 23 privileges, and you see somebody who may have the 24 infectious disease, they are a smoker, they are 25 asymptomatic of cigarette smoke or of lung cancer, A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 is there ever a situation in which you would tell that person to get a chest X-ray here? With, if I may conclude the thought, 3 Α. 4 your thought, with the intention of possibly 5 finding an early lung cancer? 6 Q. Yes. 7 Α. No. 8 And the policy of not requiring the chest X-ray at Vanderbilt, is that written down 9 10 somewhere? 11 A. It's not a policy. It has become 12 more the standard of care that in the absence of 13 specific indication, chest X-rays are not 14 productive, they're not useful, and so we are 15 doing many fewer so-called routine chest X-rays than we did when I was in training where it was 16 17 absolutely routine, everybody who was admitted to 18 the hospital got a chest X-ray. 19 What about items other than chest 20 X-rays? Have you moved to something else? 21 Oh, sure. Α. 22 Instead of the X-ray, are you using 23 more CT scans? 24 A. Oh, I beg your pardon. I was going 25 to say that routine laboratory evaluations that A. WILLIAM ROBERTS, JR. & ASSOCIATES 157 once were common, that is, they were routine, now are being done on specific indication in many 2. 3 cases, also, as a consequence of carefully looking 4 at the data. 5 Now that I have answered my question, 6 tell me yours again. 7 I think you've given me the 8 information I've requested, albeit I may not have artfully asked for it. 9 I know I asked you this earlier. I 10 11 just want to -- have you personally, and maybe 12 it's the opposite situation. Have you personally, 13 a person comes in, you looked at their lungs, you 14 see something, you said, you know, based on this 15 individual's history, I think there's a lung 16 cancer, a benign lesion on the lung or a malignant 17 lesion on the lung wherein later on we find out it 18 was a benign lesion or a calcified lesion. Have 19 you personally had that situation? 20 Α. Yes. Surely. 21 And approximately how many times has 22 that happened to you? 23 A. Oh, golly. Again, this is in the 24 context of consultative practice. I can only say 25 that over the years it has happened on occasion. A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 I'm not a stranger to that sequence. 2 It's not frequent, but we've seen them. Is it your opinion that in those Q.

instances where that happened and you were 5 consulting that you inflicted serious harm on the 6 individual? 7 Α. Well, you must recall, those are 8 circumstances in which a patient was already in 9 the institution being evaluated for more likely than not a lung problem, so the diagnosis of that 10 11 patient's problem was already the agenda. 12 Q. So that the fact that you may have 13 called it a malignant lesion as opposed to benign 14 or something else, it didn't make a difference in 15 that case, and it didn't cause serious harm because the person was there to figure out what 16 17 was wrong with their lungs anyway? 18 Α. Yes. 19 Do you have any information on how Q. 20 many lung cancers diagnosed within the United 21 States last year were operable? 22 A. I do not. 23 In those cases that we talked about 24 where you consulted and you thought it was a lung 25 cancer or a malignant lesion or nodule, and it A. WILLIAM ROBERTS, JR. & ASSOCIATES 159 1 turned out not to be, do you recall what evidence you had in front of you at this time? Was it just 3 chest X-rays, or did it include CT scans, and ever 4 a PET scan? 5 Α. I couldn't reconstruct that right 6 here as we sit. 7 Do you recall an instance at least Q. 8 with a CT scan where you made the call with that 9 data in front of you and then later turned out to 10 be wrong? 11 Α. I couldn't recall a specific patient 12 right at the moment. 13 Q. You're not putting forth -- you're 14 not an expert on the treatment of lung cancer, are 15 you? 16 I am not. 17 A couple of things in here I need to 18 -- I saw some stuff in your pile here that I want 19 to figure out. For what and how will you rely on 20 the article I've just handed you, and for the 21 record, it's the Patts article, "Correlation of 22 Tumor Size and Survival in Patients with Stage 1 23 A," it goes on? 24 Reliance is a strong word, but it 25 certainly provided some of the background and A. WILLIAM ROBERTS, JR. & ASSOCIATES 1 reaffirmed the current statements by the NCI and 2 others that we haven't significantly improved 3 survival in lung cancer and reinforces the notion 4 that even small detection of early nodules may 5 not, as the authors say, significantly improve 6 lung cancer mortality. 7 Do you know what types of lung Q. 8 cancer, cell types were examined in the Patts 9 article? 10 When I originally read the Patts 11 article, I noted that, but I couldn't tell you

12

now.

```
13
             Q. Do you consider the subject matter of
14
       this article to fall within your area of medical
15
       expertise?
16
             Α.
                  It does not.
17
                  Other than what you -- do you know if
             Q.
18
       it's a retrospective or prospective study?
19
             A. I don't anymore.
20
                   You'd have to read it again to know?
              Q.
                  Right. But this was part of my
21
             Α.
22
       general background reading. It's not central to
23
       what I thought I was bringing to the table today.
24
                  This is one of the articles the
25
       lawyers for RJR gave you, isn't it?
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      161
1
             Α.
                   Correct.
 2
                   I'm going to hand you a document,
              Q.
 3
       it's an article by Dr. Strauss, "Screening for
       Lung Cancer: Another Look, a Different View" from
       the March, 1997 publication Chest. I just want to
 5
6
       ask you if you've ever seen it?
 7
                   I have not.
8
                   Are you prepared to discuss any of
              Q.
9
       Dr. Strauss' conclusions today?
10
             A. I am not.
11
                  Are you familiar with the Mayo Lung
             Q.
12
       Project?
13
                   Only in a very general way.
             Α.
                  Do you consider the studies that were
14
15
       performed in -- that comprised the Mayo Lung
16
       Project an area that you are an expert in?
17
             A. I'm not an expert in that area.
18
                   I handed you, this is from your
19
       stack, Dr. Schaffner, again, it's an article that
20
       deals with the Mayo Lung Project, and if you
21
       would, can you tell me for what or why you've got
22
       this document and exactly what portion of your
23
       expected testimony that forms the basis of?
24
                  Well, I think the attorneys sent me
             Α.
25
       the article in part at my request to give me some
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
       more just general background information on some
1
 2
       of the very important issues that are part of this
 3
       trial. I'm speaking to a small, if you will,
 4
       slice of the pie of the whole area, but I'd like
 5
       -- I wanted to know a bit more about this.
 6
                   This reinforces the fact that I'm not
 7
       an expert in this area, and this is not an aspect
       of the deliberations that I will be commenting on.
8
9
              Q. I just want to make sure that when
10
       this thing goes to trial you don't sit up on the
11
       witness stand and say, you know, that Mayo Lung
12
       Project, that told us A, B, C and D, and that is
13
       the gospel. Do you anticipate that?
14
                   That seems -- no, no, no. I don't
             Α.
15
       anticipate that, no.
16
                  Are you familiar with the Memorial
17
       Sloan Kettering Lung Project, the Johns Hopkins
18
       Lung Project, and the Czechoslovakian study?
19
                 No. None of those.
             Α.
20
                   None of those?
              Q.
21
                   Dr. Schaffner, you've never conducted
```

```
22
       a single study related to the effectiveness of
23
       screening for lung cancer, have you?
24
                   I have not.
              Α.
25
                   Do you agree that 40 percent of lung
              Q.
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
       cancers can be detected on an X-ray in Stage 1 of
 1
       the disease?
 3
              Α.
                   I have no opinion on it.
 4
              Q.
                  Do you have an opinion or do you
 5
       agree that 70 to 80 percent of resected Stage 1
 6
       lung cancers result in long-term survival?
 7
                  I have no opinion on it.
             Α.
                  I would like to talk to you about, do
 8
 9
       you do any screening for chronic obstructive
10
       pulmonary disease in your practice?
11
             Α.
                   No.
12
                    But that's because of the nature of
13
       my practice rather than any -- that's not a
14
       response that's substantive to the question.
15
             Q. You don't, your area of practice
16
       doesn't see a lot of that?
17
                  Well, we see infectious diseases as
             Α.
18
       they complicate patients who have that disease,
19
       but I'm not a pulmonologist, and our environment
20
       people who have principally their main problem is
21
       chronic obstructive disease would be taken care of
22
       by either general internists or pulmonologists.
23
                 Would you refer to those experts to
24
       discuss appropriate screening mechanisms for
25
       chronic obstructive pulmonary disease?
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      164
                   Appropriately qualified experts in
 2.
       that area, certainly.
 3
                  And do you consider yourself one of
 4
       those individuals?
 5
             Α.
                   I do not.
 6
                   Do you consider yourself an expert in
 7
       heart disease such that you can discuss the
 8
       various modalities for screening for heart
 9
       disease?
10
             Α.
                   No.
                  Does any part of your practice
11
             Q.
12
       utilize exercise stress tests?
13
             A. No.
14
                   I want to go back. A few times
15
       during the break, I just want to ask you, did you
       discuss the substance of your testimony with
16
17
       counsel at any of the breaks?
18
             Α.
                   Absolutely not. I was so instructed
19
       before this began.
20
                    Okay. They did a good job then.
21
                    What did you do -- obviously, you
22
       indicated that either last night or over the
23
       weekend you went through this stack of documents
24
       that we identified for the record. What else did
25
       you do in preparation for this deposition today?
              A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      165
 1
                   Over this weekend?
              Α.
 2
                   No. In addition to all of that.
              Q.
                    I'm not sure what you are getting at.
              Α.
```

All right. You reviewed all of the Q. 5 materials? 6 Since we began here? Or how do you 7 mean? No, no, no. I wanted to make sure 8 that -- well, let's see. You reviewed your 9 report, right? 10 11 Α. When? 12 In preparation, at any time in Q. 13 preparation for our meeting here today, me asking 14 you the questions, or maybe not me, but somebody 15 asking you the questions, you had to do something 16 to get ready, I presume? 17 A. Indeed. 18 Q. And I'm assuming somebody contacted 19 your office and said, hey, Dr. Schaffner, you're 20 going to be interrogated on the 28th. Are you 21 going to be ready? 22 Α. That's correct. 23 Did the lawyers or did anybody 24 instruct you what you should do to prepare for the 25 deposition? A. WILLIAM ROBERTS, JR. & ASSOCIATES 166 1 Not in any specific way, but I had 2 discussions with the attorneys, and I reviewed the 3 materials. 4 Was it the two attorneys that are Q. 5 here with us today? 6 Α. Mr. O'Tuel and Ms. Susan Crooks. 7 When did you meet with them? Q. 8 I met with Mr. O'Tuel -- let's see. Α. 9 Early last week, and with Mr. O'Tuel and Ms. Crooks late last week. I can't tell you whether 10 it was Thursday or Friday anymore, and then both 11 12 before those meetings and over the course of the 13 weekend, this being a Monday today, for the record, I reviewed these materials yet again. 14 15 At any time has Mr. O'Tuel's firm or Q. 16 other lawyers actually videotaped you and asked 17 you questions while you were on the videotape and 18 later showed it to you, and kind of said, you know, this is good, this is bad, or let you make 19 20 those determinations for yourself? 21 Α. No. 22 Other than, did the attorneys go over Q. 23 questions and answers with you in preparation for 24 the deposition? 25 Α. Yes. A. WILLIAM ROBERTS, JR. & ASSOCIATES Did they direct your attention to --1 2 I know I've only talked about some of the items in 3 the stack of paper here. Did they specifically 4 direct your attention to various sections or 5 portions of articles or texts and the like? 6 I don't recall them doing that, no. 7 I think we discussed the issues, and they asked me tough questions. They pretended they were you. 8 9 What were some of the questions they Q. 10 asked you that I didn't? 11 I think you've asked many more, all 12 those and more.

```
13
                  Dr. Schaffner, in general, as it
             Q.
14
       relates to preventive medicine, do you think it's
15
       not a good idea to try and do something to detect
16
       lung cancer earlier?
                   I think it's a great idea to try to
17
18
       detect all diseases early as possible if we can do
19
       something about the outcome once we have detected
20
       the disease and we don't do so at unwarranted risk
21
       or in the societal context expense.
22
             Q. But you would agree with me that lung
23
       cancer is by far the largest preventable disease
24
       or is a preventable disease that causes the
25
       largest number of deaths per year in the United
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
                                                      168
 1
       States?
                   MR. LATHAM: Object to the form of
 2.
 3
       the question.
                   THE WITNESS: Oh, dear, I don't know
 5
       if I can agree, if I have enough knowledge of all
       the causes of preventable mortality in my brain to
 6
 7
       be able to agree with that statement.
 8
       BY MR. JEKEL:
9
                  Do you know how many deaths lung
              Q.
10
       cancers account for in the United States in any
11
       given year?
12
                   No. I can't give you that number.
13
                   Would it surprise you if it was over
14
       140,000?
15
             Α.
                   No.
16
                  Would you agree with me that lung
             Q.
17
       cancer is a preventable disease?
18
             A. Yes. Some forms of lung cancer, yes.
19
                  And, again, you don't have any
       information as it relates to all lung cancers, the
20
21
       percentage of those that are related to smoking
22
       versus other causes?
23
                    I don't.
             Α.
2.4
                   MR. JEKEL: Well, I think that's all
25
       I have. I would like to at least reserve on the
             A. WILLIAM ROBERTS, JR. & ASSOCIATES
       record, I'm sure this would be something a judge
 1
       or counsel takes up, but if Dr. Schaffner is going
 2
 3
       to issue a supplemental report based on changes in
 4
       discovery and all of the limitations he had in his
 5
       report that we at least be given an opportunity to
 6
       discuss those supplements.
 7
                   MR. LATHAM: We'll decide that at a
 8
       later date.
 9
                   MR. JEKEL: Well, I got it on the
10
      record.
11
                   Dr. Schaffner, thank you very much.
12
       I appreciate your cooperation.
13
                    MR. LATHAM: No questions for us.
                    {\tt MR.} JEKEL: Anybody on the phone have
14
15
       any questions?
16
                    ATTORNEY ON PHONE: No.
17
                    Is the court reporter still there?
18
                    MR. JEKEL: Make requests for copies
19
       of transcripts, please.
20
                    (Whereupon, the deposition was
21
      concluded at 5:33 p.m.)
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22	
23	
24	
25	
	A. WILLIAM ROBERTS, JR. & ASSOCIATES 170
1	FURTHER THIS DEPONENT SAITH NOT.
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4	SWORN to before me when taken,
5	August 28, 2000.
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11	Nancy Satoloe, Notary Public
12	State of Tennessee at Large
13	. 10.05.00
14	My commission expires: 10-25-03
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16 17	
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	A. WILLIAM ROBERTS, JR. & ASSOCIATES
1	171 CERTIFICATE
2	
3	I, WILLIAM SCHAFFNER, MD, having read the
4	foregoing deposition, Page 1 through Page 170, do
5	herewith certify said testimony is a true and
б	accurate transcript, with the following changes
7	(if any):
8 9	PAGE LINE SHOULD HAVE BEEN
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21	WILLIAM SCHAFFNER, MD
22	
23	Notary Public
24	My commission expires:
25	Date of Deposition: August 28, 2000 A. WILLIAM ROBERTS, JR. & ASSOCIATES